September 22, 2022 - Alaska Board of Pharmacy Meeting - Day 1

Alaska Division of Corporations, Business and Professional Licensing
https://us02web.zoom.us/meeting/register/tZMscemtrjwiGtP4XtYOfDDhb7SvvHQcL5xa
Sep 22, 2022 9:00 AM - Sep 22, 2022 4:30 PM AKDT

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NABP
National Association of Boards of Pharmacy

847/391-4406
Fax: 847/375-1114

1600 Feehanville Dr
Mount Prospect, IL 60056
help@nabp.pharmacy

TO: EXECUTIVE OFFICERS – STATE BOARDS OF PHARMACY

FROM: Lemrey “Al” Cater, Executive Director/Secretary

DATE: June 23, 2022

RE: Healthcare Distribution Alliance Pharmaceutical Cargo Security Coalition Fraud Alert

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The Healthcare Distribution Alliance (HDA) Pharmaceutical Cargo Security Coalition (PCSC) recently released a new fraud alert that outlines some new methodologies that are being used to divert both small and large drug shipments. These schemes involve the impersonation of regulatory personnel, including individuals from state boards of pharmacy and departments of health. The attached alert outlines specific details about these schemes.

In addition, PCSC requests that boards report any such activity or other schemes to Chuck Forsaith at cforsaith@hda.org so it can be shared with law enforcement.

Attachment

cc: NABP Executive Committee

FRAUD ALERT: DISTRIBUTOR/CUSTOMER PRODUCT ORDERING SCHEME

Version 2 (Updated June 2022)

PCSC

HDA Pharmaceutical Cargo Security Coalition

BACKGROUND

Since December 2020, there have been reports of both distributors as well as several of their pharmacy customers receiving telephone calls and/or emails as part of a sophisticated "phishing" scam to unlawfully divert pharmaceutical goods in transit.

These scams are not new. Once largely focused on trying to obtain products related to diabetes testing and treatments, the attempts now include prescription medications and medical devices.

The individuals making the calls identify themselves as employees (or affiliates) of a particular distributor or of the pharmacy customer to secure account and other sensitive information, including: specific account information, account login credentials, employee names associated with accounts, contact email addresses and/or a pharmacy's federal or state license number. The scammers ultimately use that information to engineer the diversion of products as a misshipment — or the false reclamation of a defective product.

The illicit tactic used is known as "social engineering," or the use of deception to manipulate individuals into divulging confidential corporate or personal information that may be used for fraudulent purposes. Criminals use social engineering tactics because it is usually easier to exploit the natural inclination to trust than it is to decipher ways to hack into a company's IT systems.

The pharmaceutical and healthcare products most recently targeted have included anti-depressant, blood thinning, arthritis and HIV drugs as well as AED defibrillator machines, stethoscopes and blood pressure monitors.

METHODOLOGY: PHARMACIES

There are several methods being used to scam pharmacy customers. In one of the most recent scenarios, the scammer will telephone a pharmacy and pretend to represent the state's Board of Pharmacy or Board of Health. In those scenarios, the person calling (many times, a female) asks the pharmacy representative a number of questions — several of which begin as routine and can be characterized as disarming, such as: confirming the pharmacy's business address, hours of operation, phone numbers and who the principal contacts are, among others. It isn't long before the caller eventually asks questions such as the names of the pharmacy's primary and secondary wholesalers, the types and cadence of their business interactions with their wholesalers; in some instances, the caller asks for account numbers and account passwords. On certain calls, the perpetrator uses the excuse that the Board of Pharmacy needs such information because they are responsible for notifications of product recalls.

Another method the scammers will use is to pose as a manufacturer. In this version of the scam, the perpetrator will initially telephone a pharmacy and report a product issue that is stated to be the manufacturer's responsibility. The scammer informs the pharmacy representative that certain products they have recently received may need to be replaced but, if that becomes the case, a credit will be issued through the original distributor.

The scammer (still acting as a manufacturer representative) then requests the pharmacy's distributor account information to be able to issue such a credit. The scammer further informs the pharmacy that the distributor has verified this process through the manufacturer.

Finally, the bad actors may attempt wire fraud. They will contact pharmacy customers, again pretending to be a distributor representative, and request to change traditional payment methods, such as asking the customer to send payment to a new or unfamiliar wire account.

All types of pharmacies have been targeted in these scams — large country-wide commercial operations, small-town single proprietor businesses and, more recently, hospital and university pharmacies.

METHODOLOGY: DISTRIBUTORS

A scammer will call a distributor directly "phishing" for account information by pretending to verify a pharmacy customer's licensure. They may pose as a vendor or try to impersonate State Boards of Pharmacy or other distributor employees, stating that they need account numbers so they can access correct invoices.

In certain instances, the scammers have used phrases such as, "there has been a glitch in the system," and they have asked a distributor's customer service representative to place the desired order themselves.

In some cases, where the scammer does offer an account number on their own, it has been found that the particular account does not have a previous history for the item they are requesting in an order — or that the account itself is old and has not been used for some time, or is closed.

Scammers also may try to create a new customer account, or change a customer's account information to their advantage by:

- Requesting to add additional names to an account;
- Changing or substituting different business addresses;
- Changing or substituting different account telephone numbers; or,
- Applying for a new line of credit.

THE DIVERSION ITSELF

Once the scammers have obtained pharmacy customer account credentials, they use that information to place what would appear to be a legitimate product order with the pharmacy's principal (or secondary) distributor. This can be done over the phone or online, as the scammer would, at that point, have the accurate identification information to place an order.

If the scammer is successful in creating the impression within the distributor's operations that a legitimate order has been placed by a pharmacy customer — and the distributor processes the order for shipment — the bad actors will then contact the pharmacy again, but now purport to be a distributor representative. In this conversation, the scammer will indicate that the pharmacy will be receiving a shipment that has been sent in error, or that a defective product has been shipped to them, that will need to be replaced.

The scammer will then tell the pharmacy representative that the distributor will be sending a courier to pick up the order to have it returned, reassuring the pharmacy customer that they will not be charged for the misshipment or will receive full credit for any defective product that requires a return.

The courier sent to make the pickup is not aware of the illicit activity, having simply received a routine request for a parcel pickup. The courier is most always an entity that the pharmacy customer has never used before.

The courier also ends up being scammed when they are contacted by the bad actor, again posing as a distributor representative, and told to deliver the return parcel(s) to a different address — typically that of a repackager, not the distribution center that originally shipped it.

The repackager is then scammed into sending the parcel(s) to a different location than that which was originally intended. That sequence of courier/repackager has been known to be repeated several times in a single shipment.

SCAMMER TECHNIQUES

Through **phone conversations** with distributor representatives, the scammers may appear overly confident, inpatient or even pushy — essentially acting more aggressively in attempting to get an order processed than what would typically be expected. In certain instances, the scammer may also attempt to convey a sense of urgency, which may lead the distributor representative to be sympathetic and let down their guard. In such an attempt, the scammer tries to appeal to the distributor representative's emotions by stating, "I really need this, as I'm out of supplies."

Visible telephone numbers in these communications between pharmacies and distributors (such as in a phone's "caller ID") are very frequently "spoofed" to appear as if they are being received from a legitimate entity.

Through **email communications**, the scammers similarly will "spoof" a legitimate email address by simply adding just a single letter or sequence of letters to the actual address itself. An example might be "sales@sampleaxinc.com," where an "inc" was added to what is the legitimate web address of "www.sampleax.com." The spoofed address still looks to be plausibly legitimate.

It is worth noting that in some of these email correspondences the scammers have used poor grammar, misspelled certain words or employed poor punctuation. In certain instances, the scammers inadvertently provide incorrect item numbers, omit National Drug Codes or can only spell the name of the product they are trying to order.

In all conversations/correspondences, the goal of the scammer is to gain control of the shipment without having to pay for it and then divert the parcel(s) to a different address. This may happen through direct communication to change the ship-to address or by a communication indicating the shipment is defective or was sent in error and needs to be returned — and ultimately through the medium of an unwitting courier.

These individuals are very adept at leading the person they are speaking with (whether a distributor representative or pharmacy customer) to fill in the gaps when engaging in transactional conversations. That "leading" technique subtly encourages the person they are talking with to:

1. Provide information that was not necessarily requested; or,
2. Correct certain information the scammer may have deliberately offered — in hopes that it would be clarified.

Historically, portions of this type of scam have been traced to several countries — including, but not limited to, Nigeria, Spain and Canada — but these scammers operate principally within the United States. The callers perpetuating the scam are often females. Names that have been used by the scammers in past successful interactions are "Sabrina Shaw," "Mary Wise," "Joanne Waterman," "Clancy Bidospech," "Kelly Jordan," "Rita Witt" — or simply a first name of "Allison", "Sasha" or "Susie."

Principal states where pharmacies are targeted have included Florida, California, Louisiana, Hawaii, New York, New Jersey, New Mexico, Georgia, South Carolina, Texas, Ohio, Wisconsin, Utah, Arkansas and Missouri.

RECOMMENDED ACTIONS TO PROTECT DISTRIBUTORS: RISK MITIGATION

There are several ways to validate correspondences with what appear to be legitimate distributor customers:

- Validate anything thought to be a suspicious email address: www.verifyemailaddress.org.
- Ensure any business phone number and/or address you are provided, in any type of account or credit modification/application matches a Yellow Pages "Reverse Lookup" (https://people.yellowpages.com/whitepages/phone-lookup). If the number in the yellow pages is different than the number on the credit app or account modification, call the number from www.yellowpages.com.
- Check the respective secretary of state office website for corroborating business information.
- Request a scanned or faxed copy of a specific business license, or driver's license to authenticate the request.
- Be wary of any customer using different customer names but the same address — or the same customer name but a different address.
- Be skeptical if the customer is willing to pay extra for overnight delivery but resides in a one-day delivery zone.
- Use Google Maps (www.google.com/maps) to verify any last-minute ship-to address changes.
- Consider the creation of a specific PIN for each customer, or a "security question," to strengthen the authentication process.

RECOMMENDED ACTIONS TO PROTECT PHARMACIES

Distributors can share specific actions every pharmacy should take to protect their business from this and other similar, damaging scams:

- If your pharmacy receives a suspicious call asking for account information or any type of distributor login credentials, the pharmacy representative taking the call should ask the caller for their name and phone number and simply hang up. Immediately after the call, the representative should report the details to their respective (known) distributor sales representative and request authentication. If the call is deemed suspicious the pharmacy should also notify their state's Board of Pharmacy.
- Protect your account information: login credentials, pharmacy license numbers, employee email addresses, etc., are privileged/private business information. All pharmacy personnel should be instructed not to share any of this information with anyone calling into the pharmacy. It is important to remember that a distributor will rarely, if ever, call you to request this type of private information.
- If a vendor calls the pharmacy, a pharmacy representative should call the vendor back directly, using distributor account information they already have or can reference.
- Take the time to verify all open orders with any distributor partners. If you do not see the order (in computerized tallies) that is being referenced in a call, then fraud is likely.
- If an individual purporting to be a representative of your distributor reports a defective product, call your distributor's customer support line for confirmation.
- Confirm wire payment requests with a known distributor representative before making any payment.

- Only release a return after you receive a proper, designated return authorization from your distributor partner. The only courier that should be permitted to pick up returns should be your pharmacy's regular contracted distributor driver. Call your distributor sales representative or the distributor's customer support line if a courier company, other than your regular courier driver/company, visits your site to pick up and process any return.
- Make sure your pharmacy staff is aware of these procedures so they are prepared to respond appropriately should a scammer call.
- Confirm wire payment requests with a known distributor representative before making any payment.
- Only release a return after you receive a proper, designated return authorization from your distributor partner. The only courier that should be permitted to pick up returns should be your pharmacy's regular, contracted distributor driver. Call your distributor sales representative or the distributor's customer support line if a courier company, other than your regular courier driver/company, visits your site to pick up and process any return.
- Make sure your pharmacy staff is aware of these procedures so they are prepared to respond appropriately should a scammer call.

WHAT YOU CAN DO TO ASSIST IN THESE INVESTIGATIONS

It is important in the investigation of these incidents that those pursuing criminal charges against the perpetrators know each and every time this has occurred (whether or not the attempt was successful). Helpful information would include:

- The date and time of the attempt(s).
- Whether the attempt made by phone or electronically.
- If the pharmacy — the store location as well as who within the store — spoke with the perpetrator(s).
- Any phone numbers or IP addresses that might have appeared during communications.
- The specific asks (language) used by the perpetrator.
- If contact was by phone, whether the caller was male or female.
- The name that the caller or emailer used.
- The information (if any) that may have been inadvertently provided to the perpetrator.
- Whether a voice recording of any phone conversation(s) exists with a perpetrator.
- The products discussed in any such order attempt.
- Whether any information was provided to a courier that would respond to pick up a misshipped order.

If your company has experienced a similar fraud incident or attempt, contact Chuck Forsaith of the PCSC at cforsaith@hda.org or (401) 623-1344. He can coordinate communications between your business and the appropriate law enforcement agencies. The Federal Bureau of Investigation and the U.S. Food and Drug Administration's Office of Criminal Investigations are jointly investigating these schemes, in coordination with the U.S. Attorney's Office.

The Healthcare Distribution Alliance (HDA) represents primary pharmaceutical distributors — the vital link between the nation's pharmaceutical manufacturers and pharmacies, hospitals, long-term care facilities, clinics and others nationwide. Since 1876, HDA has helped members navigate regulations and innovations to get the right medicines to the right patients at the right time, safely and efficiently. HDA's Pharmaceutical Cargo Security Coalition offers supply chain security intelligence; access to contacts from industry, government and vendor trade disciplines; physical and supply chain security assessments; a reference library of supply chain security publications, articles and related documents; as well as opportunities to attend educational events.

901 North Glebe Road, Suite 1000
Arlington, VA 22203

(703) 787-0000
(703) 812-5282 (Fax)

www.hda.org/pcsc

NABP
National Association of Boards of Pharmacy

847/391-4406
Fax: 847/375-1114

1600 Feehanville Dr
Mount Prospect, IL 60056
help@nabp.pharmacy

TO: EXECUTIVE OFFICERS – STATE BOARDS OF PHARMACY

FROM: Lemrey “Al” Carter, Executive Director/Secretary

DATE: June 23, 2022

RE: DEA Guidance Documents

The Drug Enforcement Administration (DEA) is providing the attached guidance document to all DEA registrants. The document provides information and clarification regarding DEA’s use and posting of guidance documents.

Attachment

cc: NABP Executive Committee

Drug Enforcement Administration
Diversion Control Division
Guidance Document

Title: Guidance Documents

Summary: This guidance document, which will be sent via email to all DEA registrants, provides information and clarification regarding DEA's use of guidance documents and where to find them.

Activity: Use and Posting of Guidance Documents by DEA

To Whom It Applies: DEA Registrants

Dear DEA-Registrants:

The Drug Enforcement Administration (DEA) is providing the following guidance to provide information and clarification regarding DEA's use of guidance documents. Specifically, this guidance will provide information regarding why DEA is utilizing guidance documents, where to find DEA's guidance documents, and the status of certain policy directives or regulatory interpretations issued by DEA prior to the establishment of its Guidance Document Portal.

Background

DEA's Guidance Document Portal was established pursuant to Executive Order 13891 (E.O. 13891), *Promoting the Rule of Law Through Improved Agency Guidance Documents*, signed by President Trump on October 9, 2019. The term "guidance document" was defined in E.O. 13891, in part, to mean "an agency statement of general applicability, intended to have future effect on the behavior of regulated parties, that sets forth a policy on statutory, regulatory, or technical issue, or an interpretation of a statute or regulation." E.O. 13891 required that agencies treat guidance documents as non-binding (with some exceptions), both in law and practice, take public comment into account when appropriate when formulating guidance documents, and make guidance documents readily available to the public.

In its memorandum M-20-02, dated October 31, 2019, the Office of Management and Budget directed the Department of Justice (DOJ) to publish a notice in the *Federal Register* announcing the existence of a new guidance portal and explaining that all guidance documents remaining in effect will be contained on the guidance portal. This notice was published in the Federal Register on March 13, 2020 (85 FR 14705). The DOJ guidance portal may be found at https://www.justice.gov/guidance. DEA subsequently established its own guidance document portal, which can be found at https://apps2.deadiversion.usdoj.gov/guidance/#no-back-button. This portal contains a single, searchable, indexed database that contains links to all DEA guidance documents. Thus, both the DOJ and DEA guidance portals allow members of the public to access DEA guidance documents.

To comply with E.O. 13891, DEA undertook a review of all guidance documents that were available to the public on DEA's Diversion Control Division website at that time. Memoranda, "Dear Registrant" letters, Q&As, and any other guidance documents that were not in compliance with E.O. 13891 were removed from the website.

On January 20, 2020, President Biden signed E.O. 13992 which, among other things, revoked E.O. 13891. DEA has complied with E.O. 13992, however, DEA will continue to utilize its Guidance Document Portal to provide DEA registrants a user-friendly, searchable platform for them to expeditiously locate current DEA guidance on a wide range of pertinent topics.

Guidance

- Some guidance documents issued prior to November 2019, were removed from DEA's Diversion Control Division website and are not in the guidance portal, pursuant to E.O. 13891. These guidance documents will not be restored and should be considered rescinded or not valid.

- With respect to the guidance documents that are currently listed on the Guidance Document Portal, these documents do not have the force and effect of law, and are not binding on the public in any way.

- DEA will continue to post new guidance on its Guidance Document Portal when the need arises, so DEA registrants should periodically check the portal for any new guidance that may be of interest.

We hope this information is helpful. For more information regarding DEA's Diversion Control Division, please visit htttps://www.deadiversion.usdoj.gov. Please contact the Diversion Control Division, Policy Section at (571) 362-3260 if you seek additional assistance regarding this issue or any other matter.

The contents of this document do not have the force and effect of law and are not meant to bind the public in any way. This document is intended only to provide clarity to the public regarding existing requirements under the law or Department policies.

Sincerely,

Thomas W. Prevoznik
Deputy Assistant Administrator
Diversion Control Division

EO-DEA249, June 22, 2022

NABP
National Association of Boards of Pharmacy

847/391-4406
Fax: 847/375-1114

1600 Feehanville Dr
Mount Prospect, IL 60056
help@nabp.pharmacy

TO: EXECUTIVE OFFICERS – STATE BOARDS OF PHARMACY

FROM: Maureen Garrity, Competency Assessment Director

DATE: June 23, 2022

RE: Implementation of new NAPLEX passing standard

Standard setting is the process of defining the point on the score scale that differentiates those who have the requisite knowledge, skills, and ability for safe and effective, unsupervised pharmacy practice from those who do not. The *Standards for Educational and Psychological Testing* (2014; AERA, APA, & NCME) note that "the validity of the interpretation of the test scores depends on whether the standard for passing makes an appropriate distinction between adequate and inadequate performance" (p. 176). Thus, a careful consideration of the passing standard is one of the most critical aspects of the test development cycle.

Because the passing standard is so heavily linked with the validity of the interpretation of test scores, it is common practice to re-evaluate the passing standard anytime a material change is made to an examination, such as the implementation of a new test blueprint. The National Association of Boards of Pharmacy® (NABP®) reevaluates the competency statements for the North American Pharmacist Licensure Examination® (NAPLEX®) on a regular basis; and in January 2021, NABP implemented new NAPLEX competency statements.

With the implementation of the new competency statements, NABP held a standard setting workshop on September 22-23, 2021, at NABP Headquarters in Mount Prospect, IL. A diverse panel of practicing pharmacists reviewed the results of the standard setting process and recommended a revised passing standard.

This panel's recommendation was then reviewed by NABP's NAPLEX Review Committee and Advisory Committee on Examinations prior to final approval by NABP's Executive Committee in December 2021. The revised passing standard will be implemented in January 2023; however, it should be noted that 75 remains the passing score even though NAPLEX results are now reported as pass or fail.

If you have any questions, please contact me via phone at 847/391-4400 or via email at mgarrity@nabp.pharmacy. Thank you.

cc: NABP Executive Committee
NABP Advisory Committee on Examinations
Lemrey "Al" Carter, Executive Director/Secretary
Lucinda L. Maine, American Association of Colleges of Pharmacy
Lee C. Vermeulen, American Association of Colleges of Pharmacy
Jan Engle, Accreditation Council for Pharmacy Education
DEANS – SCHOOLS AND COLLEGES OF PHARMACY

From:	Cutchins, Coleman (DOH)
To:	Sherrell, Lisa D (CED); HSS DPH OSMAP (HSS sponsored)
Subject:	RE: Rural MAT Problems
Date:	Thursday, August 25, 2022 5:09:13 PM

No problem. Have a great day!

From: Sherrell, Lisa D (CED) <lisa.sherrell@alaska.gov>
Sent: Thursday, August 25, 2022 5:09 PM
To: Cutchins, Coleman (DOH) <coleman.cutchins@alaska.gov>; HSS DPH OSMAP (HSS sponsored) <hss.dph.osmap@alaska.gov>
Subject: RE: Rural MAT Problems

Awesome Coleman, thank you for checking on that.

Lisa Sherrell
PDMP Manager

From: Cutchins, Coleman (DOH) <coleman.cutchins@alaska.gov>
Sent: Thursday, August 25, 2022 5:05 PM
To: Sherrell, Lisa D (CED) <lisa.sherrell@alaska.gov>; HSS DPH OSMAP (HSS sponsored) <hss.dph.osmap@alaska.gov>
Subject: RE: Rural MAT Problems

I talked to Fred Meyer regional Pharmacy manager. They are phasing out (by the end of the year) doing mail out from the local stores and transitioning to a central mail out pharmacy model. Mail prescriptions will still be sent, they will just originate from a different location. Coleman

---

From: Sherrell, Lisa D (CED) <lisa.sherrell@alaska.gov>
Sent: Thursday, August 25, 2022 3:22 PM
To: Cutchins, Coleman (DOH) <coleman.cutchins@alaska.gov>; HSS DPH OSMAP (HSS sponsored) <hss.dph.osmap@alaska.gov>
Subject: RE: Rural MAT Problems

I like Coleman's response. I am not sure how else to respond. I can put this correspondence on deck with the Board of Pharmacy meeting in September.

Lisa Sherrell
Prescription Drug Monitoring Program Manager
Acting Executive Administrator, Board of Pharmacy
State of Alaska – DCCED – CBPL
PDMP.alaska.gov
pharmacy.alaska.gov

From: Cutchins, Coleman (DOH) <coleman.cutchins@alaska.gov>
Sent: Thursday, August 25, 2022 2:09 PM

To: HSS DPH OSMAP (HSS sponsored) <hss.dph.osmap@alaska.gov>; Sherrell, Lisa D (CED) <lisa.sherrell@alaska.gov>
Subject: RE: Rural MAT Problems

As for addressing the concern. How about:

Thank you for informing us of this possibility. We will look into if access to MAT is changing across the state and if so see what OSMAP (and DOH) can do to support those in need.

From: HSS DPH OSMAP (HSS sponsored) <hss.dph.osmap@alaska.gov>
Sent: Wednesday, August 24, 2022 8:39 AM
To: Cutchins, Coleman (DOH) <coleman.cutchins@alaska.gov>; Sherrell, Lisa D (CED) <lisa.sherrell@alaska.gov>
Subject: FW: Rural MAT Problems

I don't know if either of you have an answer, but this seems like it could really be an issue soon. Can you help in addressing this concern?

Thank you,

-Theresa Welton-
Unit Manager- OSMAP

CDPHP-Office of Substance Misuse and Addiction Prevention | Alaska Department of Health
3601 C Street, Suite 700, Anchorage, Alaska 99503 | Mobile: 907-315-3966
theresa.welton@alaska.gov | OSMAP|

I am available via cell, email, Zoom or Teams

From: James Manners <jmanners@berniespharmacy.com>
Sent: Tuesday, August 9, 2022 5:10 PM
To: HSS DPH OSMAP (HSS sponsored) <hss.dph.osmap@alaska.gov>
Subject: Rural MAT Problems

Hello,

I want to bring a potential situation to your attention. We learned recently that Fred Meyer

pharmacies are no longer mailing controlled substances. While I understand some of the reasons for this decision, it does create a problem for folks living in communities without pharmacy services. The patient population I am most concerned about are those taking Suboxone or other partial opioid agonists as part of a Medication-Assisted Treatment regimen. As I'm sure you are aware, MAT is by far the most successful opioid treatment methodology. As I'm sure you are also aware, it is becoming increasingly difficult to obtain legitimately prescribed controlled medications, especially in rural settings. When Fred Meyer notified their patients, we were inundated with requests for help. Unfortunately we are not able to take on a large increase in controlled substance prescriptions. These patients are likely to encounter a similar situation at most other pharmacies. I am deeply concerned that these patients who are trying to escape opioid addiction will be completely unable to get their medication, greatly increasing their risk of overdose and death.

I am not advocating for Fred Meyer or any other pharmacy to be forced to mail prescriptions. It is my hope that OSMAP will have access to resources that may be able to address this problem. Please feel free to contact me with any questions you may have.

Thank you,

James Manners
General Manager
Bernie's Pharmacy, Inc.
(907)562-2138

September 12, 2022

BY EMAIL: Laura.Carrillo@Alaska.Gov

Laura Carrillo
Executive Administrator
Alaska Board of Pharmacy
P.O. Box 110806
Juneau, AK 99811

Re: USP General Chapter <825>

Dear Ms. Carrillo:

We are writing on behalf of the American Pharmacists Association, the Council on Radionuclides and Radiopharmaceuticals, Inc., the National Association of Nuclear Pharmacies, and the Society of Nuclear Medicine and Molecular Imaging to ask the Alaska Board of Pharmacy to adopt USP General Chapter <825>, "Radiopharmaceuticals – Preparation, Compounding, Dispensing, and Repackaging."[1] Our four industry and professional organizations together represent the major stakeholders in radiopharmaceutical manufacturing, nuclear pharmacy practice, and nuclear medicine practice in the U.S.

As you may know, General Chapter <825> is the first nationally applicable compendial standard for radiopharmaceutical preparation and compounding. This chapter was necessary to remedy the failure of General Chapter <797> (Pharmaceutical Compounding – Sterile Preparations) to address the unique challenges presented by radiopharmaceuticals, which require not only aseptic handling, but also radiation safety practices and attention to the abbreviated shelf-lives of these products. General Chapter <825> became official on December 1, 2020. However, it is considered merely informational until the finalization of USP General Chapters <795> and <797>, on

[1] A copy of General Chapter <825> can be downloaded from the USP web site here.

pharmaceutical compounding of non-sterile and sterile preparations, respectively, both of which contain references to General Chapter <825>. When General Chapters <795> and <797> become official, General Chapter <825> will then also become compendial. General Chapters <795> and <797> are expected to be published later in this year, and will most likely have a six-month implementation period before they become official. Of course, states are free to adopt General Chapter <825> early, as USP has encouraged them to do. To date, seven states and the District of Columbia have adopted General Chapter <825>.[2]

We strongly recommend that the Alaska Board of Pharmacy adopt General Chapter <825> at the earliest possible time – before it becomes compendial if possible, but if not, as soon as practicable afterward. As you know, pharmacies play a much larger role in the preparation of radiopharmaceuticals than conventional drugs. Unlike conventional drugs, radiopharmaceuticals must, at the very least, be dispensed as sterile, ready for administration, patient doses by the nuclear pharmacy, and usually the nuclear pharmacy also plays a major role in preparing and radiolabeling the drug so that it is in usable form. All of this must be done in a manner that protects nuclear pharmacy personnel and health care workers from radiation exposure. The outsized role of nuclear pharmacies in the preparation of usable radiopharmaceuticals gives General Chapter <825> unusual importance among pharmacy standards. The General Chapter ensures the safety, efficacy, integrity, and quality of radiopharmaceuticals by establishing facility and engineering controls, equipment, personnel training and qualifications, and procedural standards for processing radiopharmaceuticals. It also sets forth radiation safety standards to protect the nuclear pharmacy personnel engaged in these activities. For sterile preparations, which comprise the great majority of radiopharmaceuticals, the standards also ensure aseptic handling practices to protect the safety of patients. Chapter <825> is the standard written specifically for our industry and is state of the art. The sooner it is adopted and implemented by all states, the better and more consistent will be nuclear pharmacy practice, and the safer will be nuclear pharmacy personnel.

Another reason for our urgency in requesting your state's prompt adoption of General Chapter <825> is that state standards for nuclear pharmacy practice, and for inspection of nuclear pharmacies, have become not only inconsistent among states, but also confusing within particular states. In certain states, nuclear pharmacy inspectors are unsure whether to enforce the old General Chapter <797>, new General Chapter <797>, new General Chapter <825>, or state-specific standards that are different from all of these. As a result, within a single state, different nuclear pharmacies are being held to different standards by different inspectors. The problem of inconsistent standards is magnified for nuclear pharmacy providers that operate in multiple states.

[2] The states are Connecticut, Iowa, Kentucky, Mississippi, New Mexico, Ohio, Washington, and the District of Columbia. In addition, 10 states are currently discussing adoption of General Chapter <825>: California, Idaho, Louisiana, Maine, New Jersey, New Mexico, South Dakota, Utah, Vermont, and Wyoming.

We recognize that Alaska will need time to incorporate General Chapter <825> into its pharmacy regulations and/or policies, which is all the more reason to start the process now. We urge you to take the necessary steps to promptly adopt General Chapter <825> in Alaska. For your convenience, we have attached a simple model regulation that can be used to incorporate General Chapter <825> into Alaska's pharmacy regulations.

Please do not hesitate to contact Michael Guastella at michael.guastella@corar.org if you have any questions about our request.

Sincerely,

David Barnes, RPh
Nuclear Special Interest Group Coordinator
The American Pharmacist Association
(APhA) Nuclear Pharmacy Practice SIG

Michael J. Guastella, MS, MBA
Executive Director
Council on Radionuclides and Radiopharmaceuticals, Inc.

Jeff Norenberg, RPh, PharmD, PhD
Executive Director
National Association of Nuclear Pharmacies

Munir Ghesani, MD, FACNM, FACR
President
Society of Nuclear Medicine and Molecular Imaging

Model Pharmacy Regulation

(x) A nuclear pharmacy engaged in the preparation, compounding, dispensing, or repackaging of radiopharmaceuticals for human or veterinary use shall comply with United States Pharmacopeia (USP) General Chapter <825>, entitled "Radiopharmaceuticals – Preparation, Compounding, Dispensing, and Repackaging".

From: Strait, Ashley L.
To: Carrillo, Laura N (CED)
Subject: Quick question regarding nonresident wholesale permit [QBLLP-ACTIVE.FID39389093]
Date: Friday, September 9, 2022 11:40:04 AM
Attachments: image001.png

Hi Ms. Carrillo,

I hope this email finds you well. We have a quick question regarding the out-of-state wholesale distributor application. It is our understanding that one of the prerequisites to obtaining a nonresident wholesale distributor permit is a home state permit. However, as you know, many states will not issue a permit if the state does not regulate or license certain products, such a prescription medical devices that do not contain any drugs. Specifically, Wisconsin will not issue a permit to a wholesaler that does not store or distribute any drugs (see guidance below from Wisconsin Board of Pharmacy website):

Prescription Medical Device Distributors

No longer need a wholesale distributor of prescription drug license to ship medical device products into Wisconsin. Print this web page for your records verifying no license is needed.

Prescription Medical Device or Drug Manufacturers

- Need to hold a WI Drug or Device Manufacturer license only if your facility is physically located in the state of WI. Print this web page for your records verifying no license is needed.
- No longer need to hold the Wholesale Distributor of Prescription Drug license. Print this web page for your records verifying no license is needed.
- Manufacturers must maintain a list of distributors of record and update the list monthly.

In light of Wisconsin's position, would the applicant be permitted to provide the above language from the Wisconsin Board website, or confirmation from Wisconsin in lieu of a home state permit? This would indicate and support the applicant's position that it is in compliance with its home state. We are hopeful this confirmation would be sufficient as the facility fully intends to be in compliance with Alaska Pharmacy Law and obtain the required wholesale distributor permit.

We would sincerely appreciate your thoughts.

Thank you in advance for your time!

Ashley

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Ashley Strait / Attorney
Pronouns: She/Her/Hers

Ashley.Strait@quarles.com / LinkedIn BIO vCard
Quarles & Brady LLP
One Renaissance Square, Two North Central Avenue, Suite 600 / Phoenix, AZ 85004-2322
Office 602-229-5209 / quarles.com / quarles.pharmacy
Fax 602-420-5175
Assistant Cindy Ferchaud (602) 229-5612

VISIT our COVID-19: Guidance for Clients page for the latest updates from Q&B attorneys

Office of Governor
MIKE DUNLEAVY

Fact Sheet

Board: Controlled Substances Advisory Committee

Board identification number: 272

Department: LAW

Authority: AS 11.71.100

Status: Active

Sunset date:

Requirements: No Legislative Confirmation or Financial Disclosure required

Prohibitions: None

Term: 4 years

Chair: The president of the Board of Pharmacy or the president's designee is the chair of the committee

Description: The committee consists of 9 members: the Attorney General or the Attorney General's designee; the Commissioner of Health and Social Services or the Commissioner's designee; the Commissioner of Public Safety or the Commissioner's designee; the President of the Board of Pharmacy or the designee of the President who shall also be a member of the Board of Pharmacy; a peace officer appointed by the Governor after consultation with the Alaska Association of Chiefs of Police; a physician appointed by the Governor; a psychiatrist appointed by the Governor; and two individuals appointed by the Governor.

Function: To evaluate the effectiveness of current programs, budget and appropriations, enforcement policies and procedures, treatment, counseling, and regulations regarding controlled substances and to further make recommendations to the Governor, Alaska Court System and Legislature based upon their findings.

Special facts: Five members of the committee constitute a quorum, except that a smaller number may adjourn a meeting in the absence of a quorum.

Compensation: Standard Travel and Per Diem

Meetings: To be held at the call of the chairman, and are required to meet at least twice a year.

For further information and to reach individual members, contact:

Katholyn Runnels
Assistant Attorney General
310 K Street, Suite 601

Anchorage, AK 99501
Phone: 907-269-6250
Fax:

Board Roster

From: Schaber, Ashley R
To: Carrillo, Laura N (CED)
Cc: "Ramsey Bell"
Subject: Wellbeing Subcommittee Action Items
Date: Wednesday, September 7, 2022 9:43:30 AM

Hi Laura!

We've been intermittently meeting as a subcommittee since the June Board of Pharmacy meeting. We have a few items to bring back to the Board for the September meeting (in addition to a general report).

- Take *Pharmacists Fundamental Responsibilities and Right*s document back to both the BOP and AKPhA for review/approval. (https://www.pharmacist.com/pharmacistsresponsibilities)
    - We would like to discuss this document as a Board. There have been several Boards and Associations who have officially signed onto this document. We think this could help open up conversations between pharmacists, employers, the Board, and the Association about the importance of workplace wellbeing in general.
- BOP meetings- sending information to licensees
    - Laura- would you be able to send out the date and information for the September BOP meeting (and other meetings in the future)? This way licensees will have the information and can attend or make public comment if desired. I know it's on the BOP website, but we think information being emailed out to licensees would help increase awareness.

Thank you!

Ashley

THE PHARMACIST'S FUNDAMENTAL RESPONSIBILITIES AND RIGHTS

Approved by the Boards of the
American Pharmacists Association and the National Alliance of State Pharmacy Associations (June 2021)

A list of organizations in supported of the Pharmacist's Fundamental Responsibilities and Rights can be found at www.pharmacist.com/pharmacistsresponsibilities

PREAMBLE

As members of the patient-centered health care team, pharmacists are accountable for the appropriate use of medications to treat acute and chronic conditions and population health-programs that work to prevent medication and health related misadventures. Pharmacists improve patient outcomes by assuming responsibility for:

- Appropriate use of medications using evidence-based guidelines.
- Facilitating achievement of patients' health and medication-related goals.
- Promoting prevention and wellness strategies that improve patient health and overall health outcomes.
- Designing and overseeing safe, accurate, and timely medication distribution systems.
- Providing high-quality, compassionate, cost-effective care.[1]

These principles and the document as a whole, prepared and supported by pharmacists, are intended to state publicly the fundamental rights that are essential to fulfill their professional responsibilities as outlined in the *Oath of a Pharmacist* and the *Pharmacist Code of Ethics* and states' scope of pharmacy practice. These principles are established to guide pharmacists in relationships with employers, patients, and health professionals; and, guide those individuals responsible for establishing federal and state laws/regulations/guidance that govern pharmacy practice and healthcare delivery. These principles were developed as a tool to initiate and facilitate conversations between pharmacy staff and their employers.

PRINCIPLES

PHARMACISTS HAVE THE FUNDAMENTAL RESPONSIBILITY:

I. To practice with honesty and integrity.

A pharmacist places the health and well-being of the patient and community at the center of their professional practice. A pharmacist has a duty to fulfill their professional responsibilities as outlined in the *Oath of a Pharmacist, Pharmacist Code of Ethics,* and scope of practice requirements.

II. To seek employment that aligns with their professional goals and personal values and needs.

Pharmacists must be thoughtful when considering their personal professional goals, values, needs as they explore and review *potential* career opportunities. Pharmacists must also research and consider the work environment, values, and organizational goals of potential employers to understand how well they align with their own when *evaluating* employment opportunities.

III. To be lifelong learners to maintain professional competency and engage in the profession.

Recognizing that health care practice and therapeutics are constantly evolving, pharmacists have an obligation to pursue meaningful continuing professional development and education in order to maintain and optimize their clinical knowledge and abilities. Pharmacists must also have the support of their employer in order to pursue these opportunities.

IV. To educate their patients and the public to enhance public health.

Pharmacists are often the most accessible health care professionals in their communities and are essential to help educate patients to optimize use of their medications and achieve optimal health outcomes. Pharmacists bridge gaps in patient care throughout the health care delivery system. Pharmacists also play an active role in reinforcing consistent and reliable public health messages while helping to provide accurate health-related information to our patients in an era of abundantly available misinformation.

V. To make decisions and seek resolutions regarding workplace concerns without fear of intimidation or retaliation from their employer or supervisors.

Pharmacists have the responsibility to identify, address, and when needed elevate concerns regarding workplace issues that may compromise the safety, health or well-being of the pharmacy personnel or patients they serve. Employers and supervisors have a corresponding responsibility to encourage pharmacists and other pharmacy personnel to raise concerns about, and offer solutions to, maintain high-quality patient care and working conditions without fear of retaliation or intimidation from employers or supervisors.

-CONT

[1] Based on the Joint Commission of Pharmacy Practitioners Vision for Pharmacy Practice (Adopted 2014).

PHARMACISTS HAVE THE FUNDAMENTAL RIGHT:

I. To practice pharmacy in the best interest of patient and community health and well-being.

A pharmacist must consider the rules and regulations intended to protect the health and well-being of patients and communities while also using professional judgment in their decision making process.

II. To exercise professional judgment under the auspices of their license when delivering care to patients.

Pharmacists must have the independence to use their education and knowledge to make professional clinical decisions in the best interest of their patients. To mitigate incidents of moral distress[2], pharmacists should never be placed in a situation where they are forced to take part in patient care activities or decisions that they do not believe are in the best interest of the patient's health and/or well-being or that are in violation of pharmacy laws and/or regulations.

III. To be treated in a considerate, respectful, and professional manner by patients and supported by employers and supervisors.

Pharmacists should not be subject to behavior or work conditions that impede their independent professional judgment, or actions that compromise the best interests of the health and well-being of their patients or their status as a healthcare professional.

IV. To a workplace free of racism, discrimination, bullying, or harassment, as well as physical, verbal, or emotional abuse.

Pharmacists' workplaces should be free of discriminatory practices including but not limited to, physical abuse, emotional abuse, verbal abuse, racism, discrimination, harassment, or bullying.

V. To a working environment where the necessary resources are allocated to provide both legally required patient care services, as well as any additional enhanced patient care services offered.

Pharmacy is a highly-regulated profession which includes specific state and federal legal requirements that must be met when taking care of patients. At a minimum, sufficient time and adequate staffing are needed to safely adhere to the basic legal requirements before adding enhanced patient care services (e.g., vaccine administration, Medication Therapy Management (MTM), collaborative practice services). In addition, pharmacists should have ready access to current information and appropriate clinical and therapeutic references to support their delivery of patient care.

VI. To reasonable working hours and conditions.

Pharmacists must be permitted and encouraged to take needed breaks as well as sufficient, appropriate staff to safely complete the tasks at hand. Pharmacists should have access to tools when needed to promote and maintain physical and mental health (i.e., ergonomic work tools, stool or chair, cushioned floor mat when standing for long periods, appropriate lighting, access to appropriate restroom and lactation facilities, access to sustenance throughout the day).

VII. To have a voice in the development of metrics, and how those metrics are used as criteria for performance evaluations of all pharmacy staff.

Pharmacists should be evaluated fairly, with performance metrics and indicators that are focused on quality patient care while assuring adequate staffing is provided to meet those metrics and ensure patient safety by preventing medication errors. Meaningful performance metrics should address the quality of care provided to patients that pharmacists can directly impact and not only the cost or efficiency of services or operations.

###

[2] In 1984, Andrew Jameton coined the term *moral distress* to describe the negative feelings a nurse feels when one knows the morally correct action to take but is constrained in some way from taking this action. It is different from burnout because it deals with your moral responsibility in a situation that you evaluate and determine the right course of action and then are prevented from doing it. The *American Journal of Nursing* (July 2016) suggests that moral distress can lead to "debilitating frustration, anger, and guilt." This article indicates that system-based sources of moral distress include "restrictive institutional policies, power structures, and regulatory practices, as well as limited human and material resources." Only the last few years have publications explored moral distress in other health care professionals.

From: Janso, Lisa
Subject: District 7 Well-being Index for Pharmacy Personnel Reports
Date: Tuesday, September 13, 2022 11:07:00 AM
Attachments: image001.png
image002.png
image003.png
image004.png
image005.png
NABP Report - District 7 - Sep 2022.pdf

Good afternoon,

Well-being Index Monthly Report

Attached is the September Well-being Index (WBI) for Pharmacy Personnel report for your district. The national overall distress percent remains essentially unchanged.

This month, a comparison of distress percent by practice role is included at the beginning of the report. This looks at the distress percent from January 2020 (6 months from the launch of the WBI), September 2020, September 2021, and this month. The overall distress percent includes assessors' first assessments along with all reassessments. The 1st Assessment Only is just that - each assessor's first assessment. First Time Assessment only distress percent has been higher than that of the combination of first and reassessments perhaps indicating that as people understand their well-being and take action their reassessment scores are lower.

As a reminder, the Distress Percent measures the percentage of Well-being Index assessors whose scores indicate that they are at risk for high distress. It is a snapshot in time of those who have used the WBI tool and cannot be generalized to the profession. The WBI is not a survey, it is a tool for individuals to assess and track their well-being and access resources for information on the specific dimensions of distress.

Please feel free to share the report with the members of your board. If you have questions about the WBI or the reports, please contact APhA's April Shaughnessy at ashaughnessy@aphanet.org.

PWWR

Last week, APhA released the Pharmacy Workplace and Well-being Reporting (PWWR) Report III (available here). Since the launch of PWWR in October 2021, more than 1,100 experience reports have been submitted. APhA shared the following information regarding the PWWR report.

In this in-depth report, 174 experiences were analyzed. The positive experiences reported ranged from changes in pharmacy hours to enhanced work-life balance, to reviewing patient charts in order to determine the best medication therapy, to a workflow system that enhances patient safety and increases efficiency, to a supportive pharmacy manager. Those who submitted positive experiences indicated that these experiences would have a long-term effect on their well-being.

The primary reason for negative experiences submitted in this reporting cycle was again workplace conditions. As observed in the first two reports released, negative submissions of pharmacy staff dealing with threats and harassment from patients/consumers and work colleagues (co-workers, pharmacy managers, non-pharmacy managers, supervisors) continues to be concerning. The reported experiences ranged from verbal, emotional, and sexual harassment, physical harm (threatened or actual), and discrimination/microaggression. Additionally, work-related mental health problems were described in explicit detail perhaps signaling a larger incidence of these cases that are underreported.

A continuing concern in this analysis cycle is the reported lack of open channels of communications. Of those who submitted negative experiences, 68% indicated that they offered recommendations to management, and nearly all of them indicated that their recommendations were not considered or applied causing them to feel ignored and unvalued. Thirty-two percent did not offer recommendations because they fear retaliation, being labeled a complainer, recognition that there is little a middle manager can do, and believe that nothing will happen if reported. The disconnect between staff-level and upper management communications manifested in submission narratives was prevalent in this analysis cycle.

The learnings from the PWWR reports can be used as a discussion guide when your board holds task force or committee meetings on workplace issues. Please see www.pharmacist.com/pwwr for previous in-depth reports and monthly snapshots.

Please Note: PWWR is not a survey. It is confidential/anonymous service for pharmacy personnel to report their positive and negative experiences. PWWR is a safe space with reports collected and analyzed by the Alliance for Patient Medication Safety, a federally recognized patient safety organization (PSO). Reports are protected by the confidentiality and privilege provisions of the Patient Safety and Quality Improvement Act of 2005. Actual submission reports to PWWR cannot be disclosed or subpoenaed, and they are not subject to discovery in a legal proceeding.

If you have questions about PWWR or the reports, please contact APhA's April Shaughnesy at ashaughnessy@aphanet.org.

Best regards,
Lisa

Lisa Janso, MS
Executive Committee Manager
847/391-4462

National Association of Boards of Pharmacy
1600 Feehanville Dr, Mount Prospect, IL 60056
www.nabp.pharmacy | ljanso@nabp.pharmacy

APhA

WELL-BEING index

Well-being Index For Pharmacy Personnel

State Report For State Boards of Pharmacy

NABP District Seven States

JULY 2022

For Every Pharmacist. For All of Pharmacy.

pharmacist.com

What is the WBI for Pharmacy Personnel Distress Percent?

What is the WBI for Pharmacy Personnel's Distress Percent?

- Distress Percent is the percentage of WBI assessors with a WBI score greater or equal to 5; the validated score that indicates risk of high distress.[1]
  - Distress Percent is the percentage of those who completed the WBI who are *at risk of high distress*.
  - The Distress Percent measures those who have assessed using the WBI for Pharmacy Personnel and not generalizable to a state, district, or profession.

Why is this Important?

Pharmacy personnel identified as being *at risk of high distress* are also at a:

- 3-fold higher risk of low quality of life
- 8-fold higher risk of burnout
- 2.5-fold higher risk of high fatigue
- 2.5-fold higher risk of intent to leave their current job
- ***2-fold higher risk of medication error***

[1]*Ability of the Well-Being Index to identify pharmacists in distress.* Skrupky, Lee P., et al. *JAPhA June 2020*

DISTRESS PERCENT CHANGES

National and District

July 2022 versus June 2022

Changes in Distress Levels

As of July 2022

State	Change in Distress % June 2022 vs July 2022	Distress % July 2022	State Rank for Distress Percent July 2022
Largest Increase in Distress Percent			
Virginia	5.10%	45.23%	5
Delaware	1.62%	33.33%	27
Nevada	1.49%	59.46%	1
Vermont	0.77%	30.77%	37
Oklahoma	0.46%	35.58%	17
Largest Decrease in Distress Percent			
Puerto Rico	-2.37	45.00	6
Tennessee	-1.01	31.71	38
New Jersey	-0.84	36.89	16
District of Columbia	-0.81	30.77	36
Georgia	-0.77	33.12	31
NATIONAL	0.15%	33.13%	----

Changes in Distress Levels – District Seven

As of July 2022

	Change in Distress % Jul 2022 Vs Jun 2022	Distress % Jul 2022	Distress % State Rank Jul 2022	Change in Distress % Jun 2022 Vs May 2022	Distress % State Rank Jun 2022	Distress % State Rank May 2022	Distress % State Rank Apr 2022	Distress % State Rank Mar 2022	Distress % State Rank Feb 2022	Distress % State Rank Jan 2022	Distress % State Rank Dec 2021	Distress % State Rank Sep 2021	Distress % State Rank Apr 2021	Distress % State Rank May 2020	Distress % State Rank Apr 2020
Alaska	**-0.43%**	**30.56%**	**39**	-0.44%	38	38	33	33	49	48	48	49	49	49	49
Idaho	**-0.29%**	**34.19%**	**24**	No Change	22	22	27	25	26	31	31	40	34	40	39
Montana	**No Change**	**40.63%**	**11**	No Change	10	11	11	11	12	10	10	10	12	19 (T)	24
Oregon	**0.17%**	**33.33%**	**27 (T)**	0.18%	28	31	29	30	30	29	27 (T)	28	28	36	37
Washington	**0.24%**	**42.19%**	**9**	0.57%	8	8	9	10	10	12	11	12	11	12	13
Wyoming	**No Change**	**17.39%**	**52**	No Change	52	52	52	52	52	52	52	51	51	~	~

(T) = Tied rank with another state(s).
Note: Some historic data from 2020/2021 has been removed to allow space for current month. Refer to previous months' reports or contact ashaughnessy@aphanet.org for data.

DISTRESS PERCENT MONTHLY REPORTS
State-Specific
June 2022 versus July 2022

WELL-BEING INDEX FOR PHARMACY PERSONNEL

STATE DISTRESS PERCENT*

JULY 2022

As of July 6, 2022, the Alaska distress percent was 30.56% (ranked 39/52) with 49 assessors.

JUNE 2022

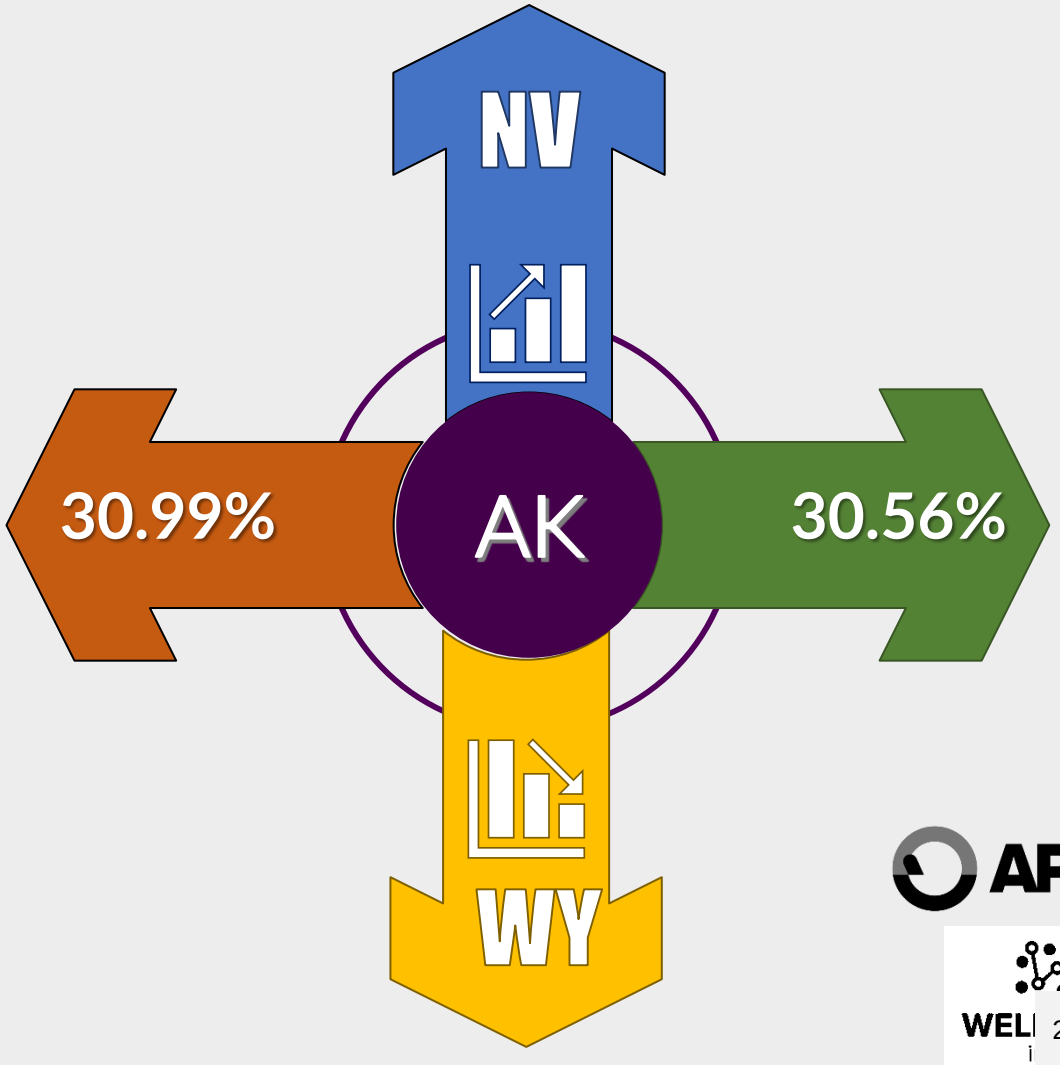
As of June 6, 2022, the Alaska distress percent was 30.99% (ranked 38/52) with 49 assessors.

STATE COMPARISON

As of July 6, 2022

Nevada is the highest at 59.46% (n=33)

Wyoming has the lowest 17.39% (n=16)



APhA

WELL 217 NG

https://app.mywellbeingindex.org/signup

Invitation Code: APhA

Distress Percent is the percentage of individuals with a Well-Being Index (WBI) score ≥5. It measures the percent of individuals that are at a high level of distress.

WELL-BEING INDEX FOR PHARMACY PERSONNEL

STATE DISTRESS PERCENT*

JULY 2022

As of July 6, 2022, the Idaho distress percent was 34.19% (ranked 24/52) with 69 assessors.

JUNE 2022

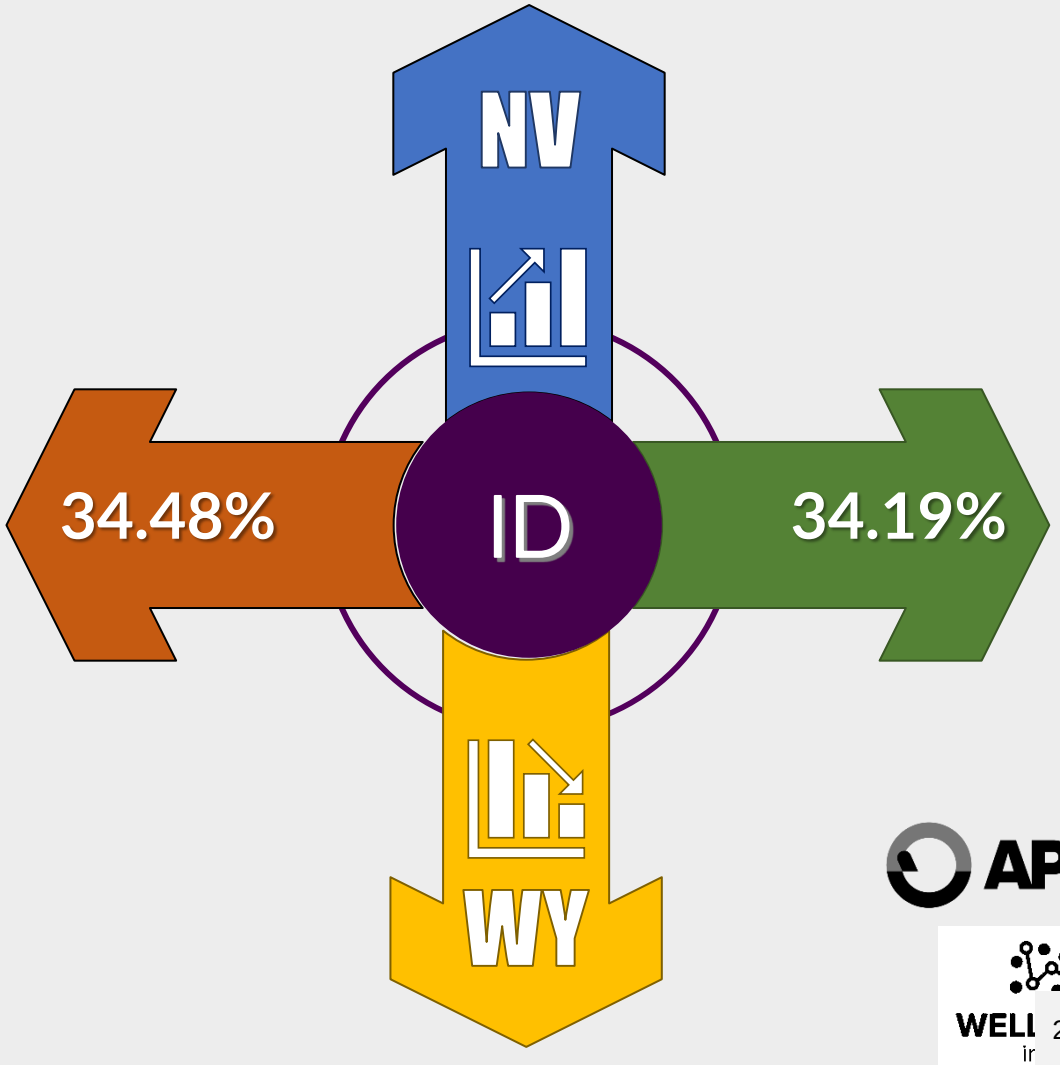
As of June 6, 2022, the Idaho distress percent was 34.48% (ranked 22/52) with 68 assessors.

STATE COMPARISON

As of July 6, 2022

Nevada is the highest at 59.46% (n=33)

Wyoming has the lowest 17.39% (n=16)



APhA

WELL 218 IG
ir
https://app.mywellbeingindex.org/signup
Invitation Code: APhA

Distress Percent is the percentage of individuals with a Well-Being Index (WBI) score ≥5. It measures the percent of individuals that are at a high level of distress.

WELL-BEING INDEX FOR PHARMACY PERSONNEL

STATE DISTRESS PERCENT*

JULY 2022

As of July 6, 2022, the Montana distress percent was 40.63% (ranked 11/52) with 26 assessors.

JUNE 2022

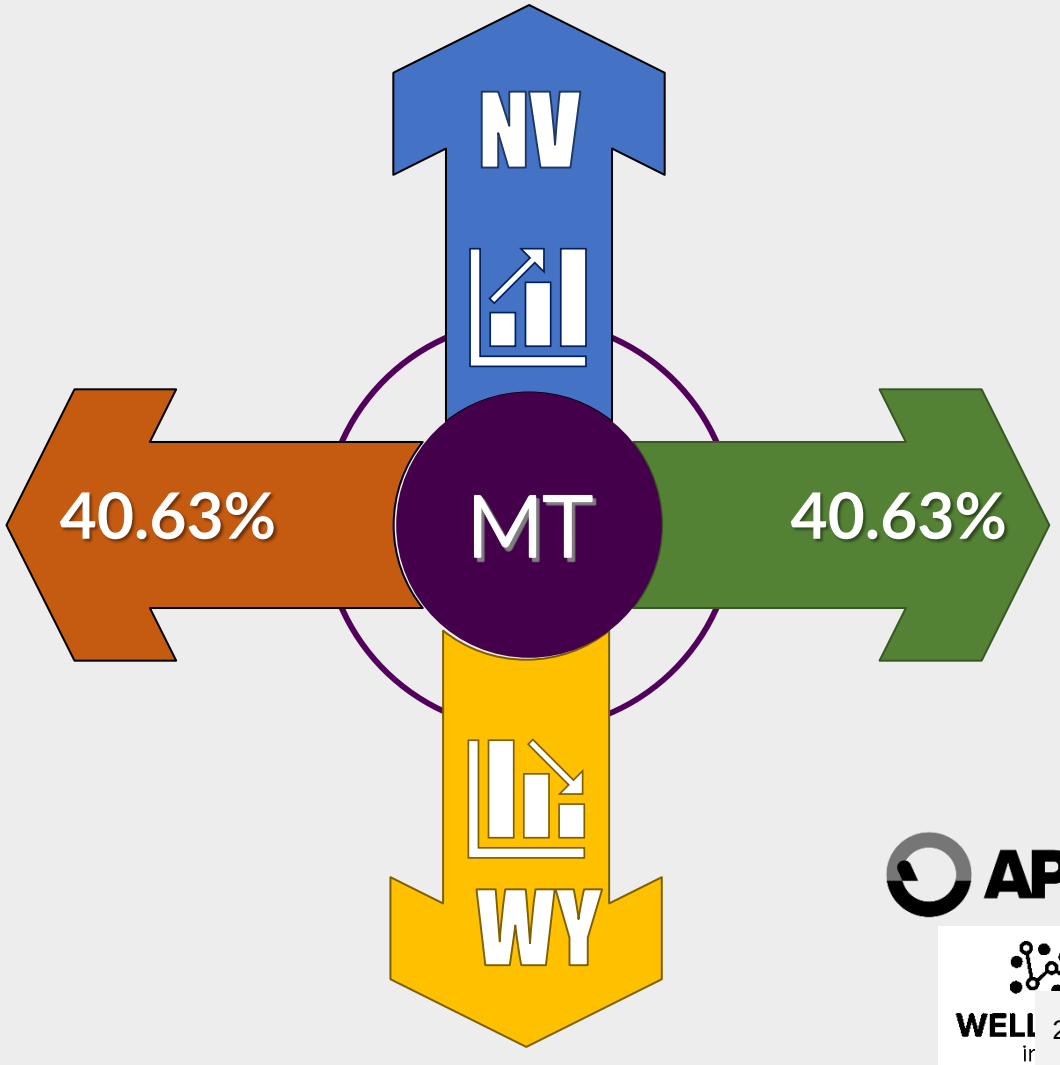
As of June 6, 2022, the Montana distress percent was 40.63% (ranked 10/52) with 26 assessors.

STATE COMPARISON

As of July 6, 2022

Nevada is the highest at 59.46% (n=33)

Wyoming has the lowest 17.39% (n=16)



APhA

WELL 219 IG
ir
https://app.mywellbeingindex.org/signup
Invitation Code: APhA

Distress Percent is the percentage of individuals with a Well-Being Index (WBI) score ≥5. It measures the percent of individuals that are at a high level of distress.

WELL-BEING INDEX FOR PHARMACY PERSONNEL

STATE DISTRESS PERCENT*

JULY 2022

As of July 6, 2022, the Oregon distress percent was 33.33% (tied ranked at 27/52) with 95 assessors.

JUNE 2022

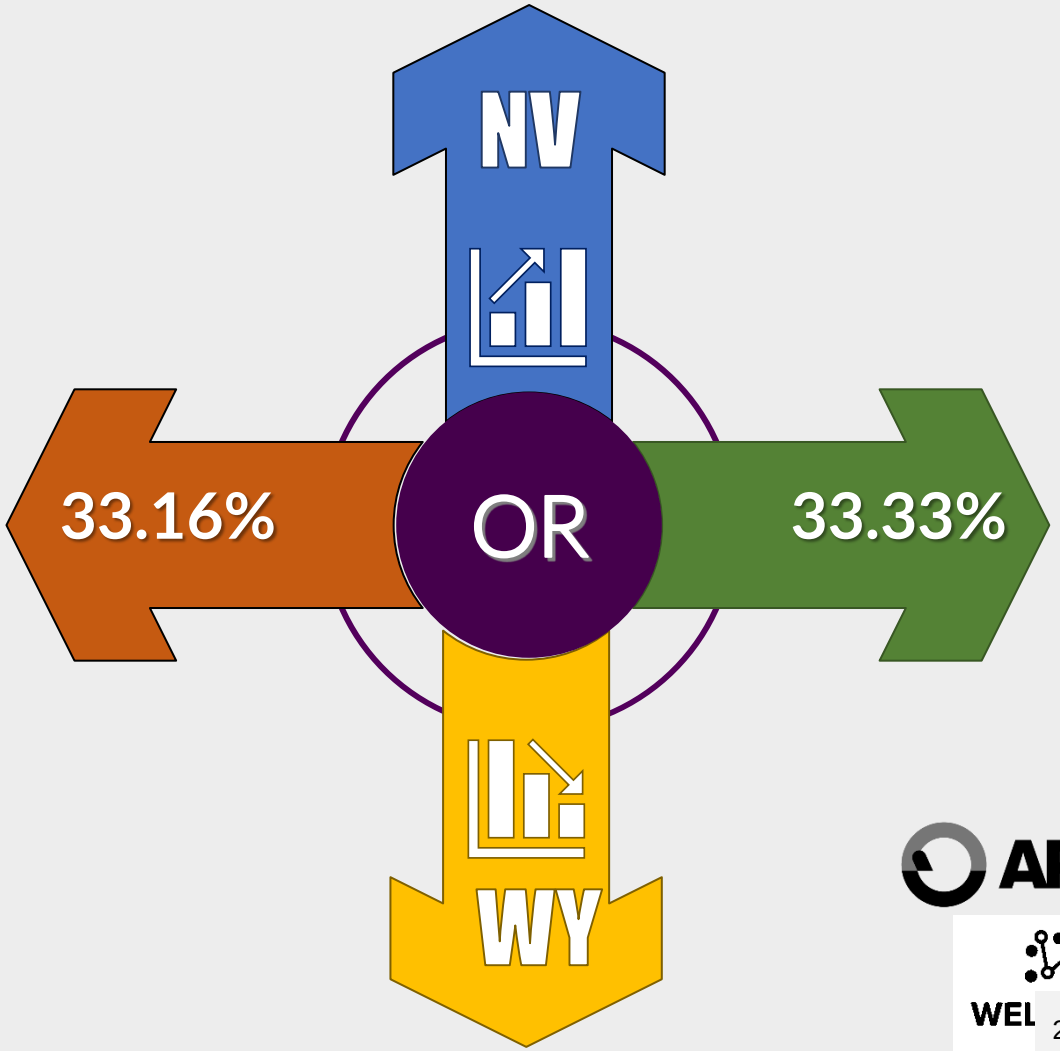
As of June 6, 2022, the Oregon distress percent was 33.16% (ranked 28/52) with 94 assessors.

STATE COMPARISON

As of July 6, 2022

Nevada is the highest at 59.46% (n=33)

Wyoming has the lowest 17.39% (n=16)



APhA

WEL 220 NG

https://app.my org/signup

Invitation Code: APhA

Distress Percent is the percentage of individuals with a Well-Being Index (WBI) score ≥5. It measures the percent of individuals that are at a high level of distress.

WELL-BEING INDEX FOR PHARMACY PERSONNEL

STATE DISTRESS PERCENT*

JULY 2022

As of July 6, 2022, the Washington distress percent was 42.19% (ranked 9/52) with 153 assessors.

JUNE 2022

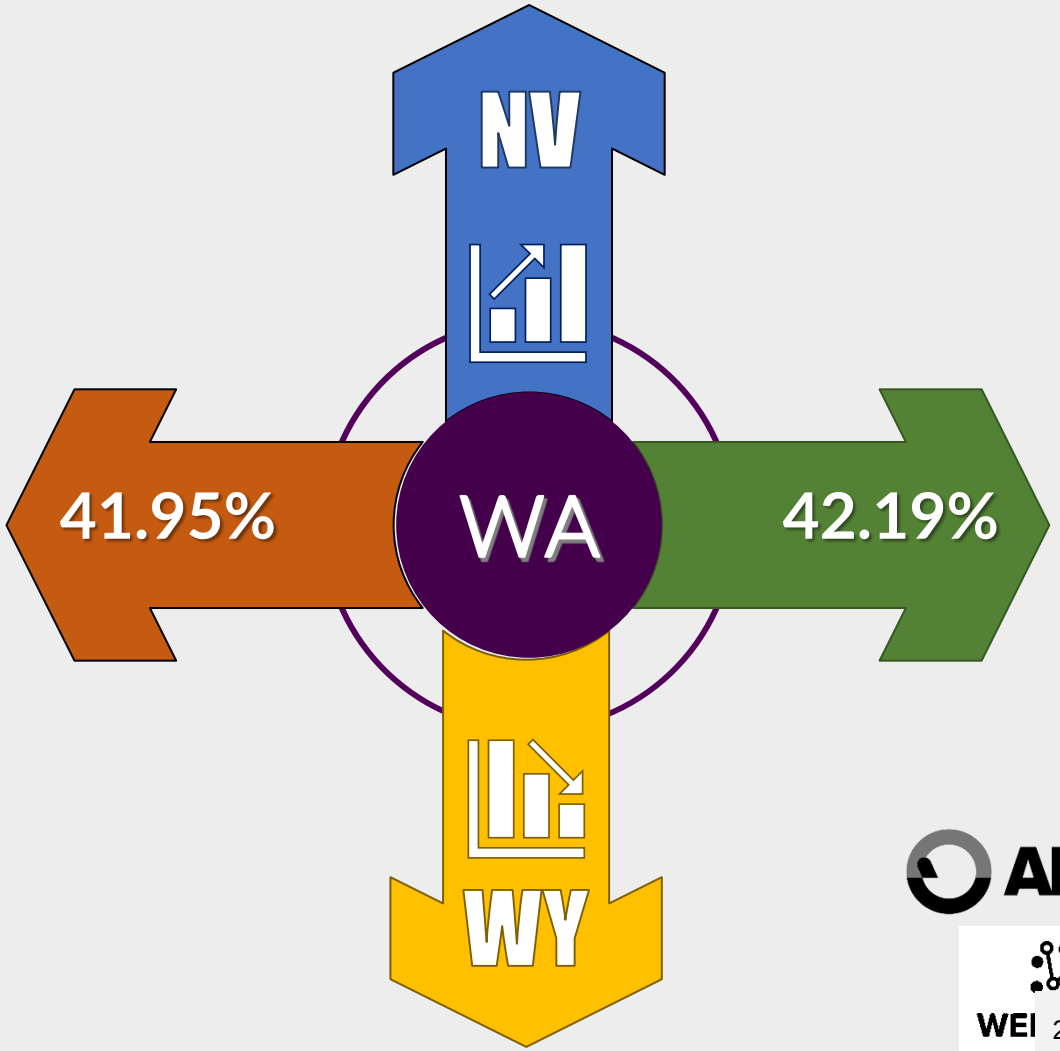
As of June 6, 2022, the Washington distress percent was 41.95% (ranked 8/52) with 153 assessors.

STATE COMPARISON

As of July 6, 2022

Nevada is the highest at 59.46% (n=33)

Wyoming has the lowest 17.39% (n=16)



APhA

WELL-BEING INDEX 221

https://app.mywellbeingindex.org/signup
Invitation Code: APhA

Distress Percent is the percentage of individuals with a Well-Being Index (WBI) score ≥5. It measures the percent of individuals that are at a high level of distress.

WELL-BEING INDEX FOR PHARMACY PERSONNEL

STATE DISTRESS PERCENT*

JULY 2022

As of July 6, 2022, the Wyoming distress percent was 17.39% (ranked the lowest at 52/52) with 16 assessors.

JUNE 2022

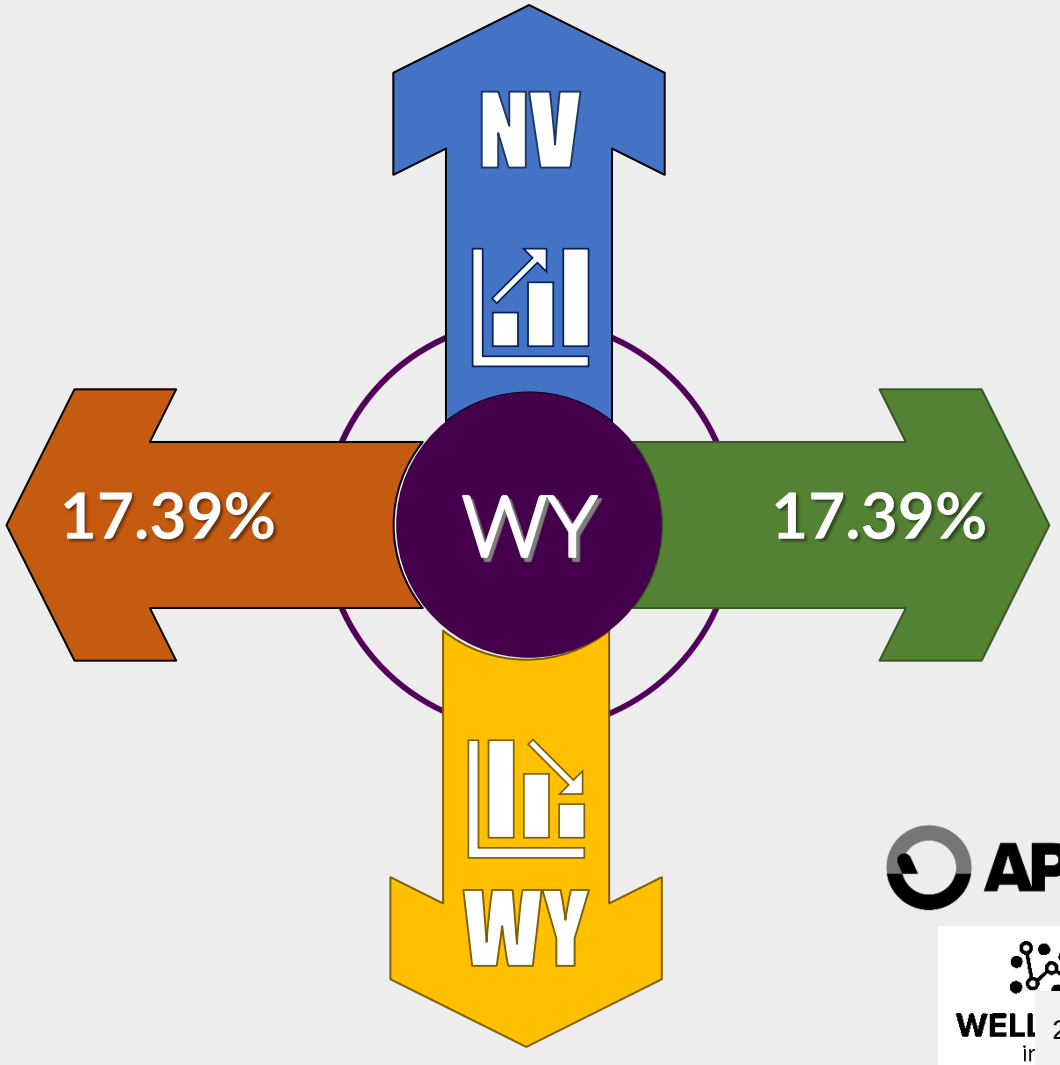
As of June 6, 2022, the Wyoming distress percent was 17.39% (ranked the lowest at 52/52) with 16 assessors.

STATE COMPARISON

As of July 6, 2022

Nevada is the highest at 59.46% (n=33)

Wyoming has the lowest 17.39% (n=16)



APhA

WELL 222 IG
ir
https://app.mywellbeingindex.org/signup
Invitation Code: APhA

Distress Percent is the percentage of individuals with a Well-Being Index (WBI) score ≥5. It measures the percent of individuals that are at a high level of distress.

Well-being Resources Promo Slides*

For Your Use in State Social Media and Periodicals

** Please do not change the content of these promotional slides*

WELL-BEING index

Burnout is real.

Take advantage of APhA's online screening tool, invented by the Mayo Clinic,
to evaluate your fatigue, depression, burnout, anxiety, and stress and assess your well-being.
It takes less than 5 minutes to answer 9 short questions.
It's 100% anonymous, free, and you do not need to be an APhA member.
Resources are available once you submit your assessment.

Well-being Index for Pharmacists, Student Pharmacists, & Pharmacy Technicians

https://app.mywellbeingindex.org/signup

Invitation Code: APhA

Or Scan

APhA

You're committed to pharmacy.
We're committed to your well-b
www.pharmacist.com/wellbe

Your experiences – positive and negative – tell a powerful story!

Your experience can be the spark that helps change and enhance the pharmacy workplace, pharmacy personnel well-being, and patient safety.

Submit your experience report to
Pharmacy Workplace and Well-being Reporting.
www.pharmacist.com/pwwr

Your report is confidential, anonymous, and protected by the Alliance for Patient Medication Safety - a recognized national patient safety organization.

Share the PWWR link with your colleagues!

perform or supervise pharmacy operations must comply with the following requirements: ( )

01. Security and Access. Maintain adequate video surveillance of the facility and retain a high quality recording for a minimum of thirty (30) days. ( )

02. Technology. The video or audio communication system used to counsel and interact with each patient or patient's caregiver, must be clear, secure, and HIPAA-compliant. ( )

03. Technical Limitation Closure. The drug outlet must be, or remain, closed to the public if any component of the surveillance or video and audio communication system is malfunctioning, until system corrections or repairs are completed. ( )

04. Exemption for Self-Service Systems. A self-service ADS that is operating as a drug outlet is exempt from the video surveillance requirement and the self-inspection requirement of this rule. In addition, if counseling is provided by an onsite prescriber or pharmacist, a self-service ADS is exempt from the video and audio communication system requirements of this rule. ( )

05. Exemption for Veterinarians. Veterinarians practicing in accordance with their Idaho practice act are exempt from this rule. ( )

303. DRUGS STORED OUTSIDE OF A DRUG OUTLET FOR RETRIEVAL BY A LICENSED HEALTH PROFESSIONAL.

Drugs may be stored in an alternative designated area outside the drug outlet, including, but not limited to, floor stock, in an emergency cabinet, in an emergency kit, or as emergency outpatient drug delivery from an emergency room at a registered institutional facility, provided the following conditions are met: ( )

01. Supervising Drug Outlet. Drugs stored in such a manner must remain under the control of, and be routinely monitored by, the supervising drug outlet. ( )

02. Secure Storage. The area is appropriately equipped to ensure security and protection from diversion or tampering. ( )

03. Controlled Substances. Controlled substances may only be stored in an alternative designated area as permitted by, and in accordance with, federal law. ( )

04. Stocking and Replenishing. Stocking or replenishing drugs in an alternative designated area may be performed by a pharmacist or prescriber, or by appropriate support personnel using either an electronic verification system or a two (2) person checking system. ( )

304. – 349. (RESERVED)

SUBCHAPTER D – RULES GOVERNING PHARMACIST PRESCRIPTIVE AUTHORITY
(Rules 350 through 399)

350. PHARMACIST PRESCRIBING: GENERAL REQUIREMENTS.

01. Education. Only prescribe drugs or devices for conditions for which the pharmacist is educationally prepared and for which competence has been achieved and maintained. ( )

02. Patient-Prescriber Relationship. Only issue a prescription for a legitimate medical purpose arising from a patient-prescriber relationship as defined in Section 54-1733, Idaho Code. ( )

03. Patient Assessment. Obtain adequate information about the patient's health status to make appropriate decisions based on the applicable standard of care and the best available evidence. ( )

04. Collaboration with Other Health Care Professionals. Recognize the limits of the pharmacist's own knowledge and experience and consult with and refer to other health care professionals as appropriate. ( )

05. Documentation. Maintain documentation adequate to justify the care provided including, but not limited to, the information collected as part of the patient assessment, the prescription record, provider notification, and the follow-up care plan. ( )

351. COLLABORATIVE PHARMACY PRACTICE.
Collaborative pharmacy practice may be performed in accordance with an agreement that identifies the parties to the agreement, the pharmacist's scope of practice authorized, and if necessary, any monitoring parameters. ( )

352. -- 399. (RESERVED)

SUBCHAPTER E – FILLING AND DISPENSING PRESCRIPTION DRUGS
(Rules 400 through 499)

400. PRESCRIPTION DRUG ORDER: VALIDITY.
Prior to filling or dispensing a prescription drug order, a pharmacist must verify its validity. ( )

01. Invalid Prescription Drug Orders. A prescription drug order is invalid if not issued by a licensed prescriber for a legitimate medical purpose, and within the course and scope of the prescriber's professional practice and prescriptive authority. ( )

02. Antedating or Postdating. A prescription drug order is invalid if antedated or postdated. ( )

03. Tampering. A prescription drug order is invalid if, at the time of presentation, it shows evidence of alteration, erasure, or addition by any person other than the person who wrote it. ( )

04. Prescriber Self-Use. A prescription drug order written for a controlled substance is invalid if written for the prescriber's own use. ( )

05. Digital Image Prescriptions. A digital image of a prescription drug order is invalid if it is for a controlled substance or if the patient intends to pay cash for the drug in whole. ( )

401. PRESCRIPTION DRUG ORDER: MINIMUM REQUIREMENTS.
A prescription drug order must comply with applicable requirements of federal law and, except as differentiation is permitted for an institutional drug order, include at least the following: ( )

01. Patient's Name. The patient's or authorized entity's name and: ( )

a. If for a controlled substance, the patient's full name and address; and ( )

b. If for an animal, the species. ( )

02. Date. The date issued. ( )

03. Drug Information. The drug name, strength, and quantity. ( )

04. Directions. The directions for use. ( )

05. Prescriber Information. The name and, if for a controlled substance, the address and DEA registration number of the prescriber. ( )

06. Signature. A signature sufficient to evidence a valid prescription of either the prescriber or, if a renewal of a previous prescription, the prescriber's agent, when authorized by the prescriber. ( )

Steps in the Board Regulation Adoption Process

Day 1

1

At an open meeting, the board votes on language to change regulations. This motion is forwarded to the Division Regulations Specialist for drafting.

Day 30

2

Once drafting is complete, the board holds another public meeting to edit or approve draft for public notice.

3

Approved language is reviewed by Division attorney.

4

Department of Law opens file.

5

Day 45

Division publishes and distributes public notice, additional regulation notice information, and proposed regulation to all licensees and interested parties. Public notice posted in newspaper and on Alaska Online Public Notice System

6

Public comment period and/or hearing (if applicable).

Day 65

7

Division Regulations Specialist compiles answers to questions and posts FAQ on the program web page.

Day 75

8

Regulations Specialist compiles public comments for distribution to board.

Day 90

9

Board holds an open meeting to review public comments, make minor changes, and adopt regulations. Substantive changes may require additional drafting and public notice (Step 2).

10

Division submits final regulation package to Department of Law for review and approval, and to the Governor's office.

11

Agency attorney reviews regulation

12

Regulations attorney reviews and either approves or disapproves regulation

Day 110

13

Unless returned by the Governor, Lt. Governor's office files approved regulation; regulations become effective in 30 days

Day 150

Once Regulations Are Effective

14a

Agency posts summary on Alaska Online Public Notice System

14b

Regulation published in Alaska Administrative Code

14c

Forms & FAQ updated on program web page

All timeframes are estimated, dependent upon staff and attorney workflow and board scheduling.

Steps in the Regulation Process for a Board and Commission (board)[1]

Beginning the Process

1. At an open meeting, the board initiates and votes on proposed regulation changes.

2. **Reason:** Identify the reason for the proposed action, such as compliance with new or changed state law. If applicable, identify the law, order, decision, or other action of the federal government, or federal or state court, if that is the basis for the proposed action. The description need only be a sentence or two.

3. **Cost information:** In the meeting minutes there must be estimated costs in the aggregate to comply with the proposed action to:

    - A private person
    - Another state agency
    - A municipality

    Cost information is described simply as an estimate of annual costs within the board's ability to determine due to its familiarity with the regulated community.

    Example: The Board of Chiropractic Examiners is proposing to add three CE credits to their continuing competency requirements for a biennial license renewal. The proposal may cost

    - A private person: $50 per applicant/licensee
    - Another state agency: None known
    - A municipality: None known

4. Within 10 days of the meeting, board staff must transmit board minutes[2] or an excerpt of the minutes, draft language or proposals, and a completed Regulations FAQ Worksheet for the proposed regulation changes requested by the board to the Regulations Specialist.

What comes next: Regulations Specialist

5. The Regulations Specialist determines if there is authority in statute to adopt the proposed regulation changes.

6. The Regulations Specialist prepares a draft of regulation changes, using the Department of Law's *Drafting Manual for Administrative Regulations* for conformity and style, and works with board staff before submitting the final draft to the board for review/approval. In some instances the draft regulation changes will be reviewed by an AAG before the final draft is submitted to the board for review/approval.

7. Once completed, the draft proposed regulation changes are presented to the board at its next public meeting to review and approve the final draft, amends if needed, and requests that the approved draft be finalized and public noticed.

Public Notice

8. NOTE: The board must **always** provide an opportunity for submission of written comments in the regulation-adoption process. Also, the board should determine if it wants to hold a public hearing on the proposed regulation changes at its next meeting. If it does, the location, date and time of the hearing needs to be included in the public notice. Public hearings are usually held in conjunction with a regularly-scheduled meeting of the board and are always recorded. Oral public hearing is optional; however, answering the following questions will help the board determine if an oral public hearing is needed:

    - Are the regulations controversial and is there likely to be substantial public interest in them?
    - Would those most affected by the regulations be better able to participate if an oral hearing were held?
    - Would the board benefit from a face-to-face or teleconferenced opportunity to receive comments on the proposed regulations from interested persons?

9. Regulations Specialist sends notice to Alaska Dispatch News (or other newspapers if warranted) for publication, all interested parties, and licensees, if warranted. The Regulations Specialist posts the notice on the Alaska Online Public Notice System, electronically transmits a copy of the notice and proposed regulation changes to all incumbent legislators and the Legislative Affairs Agency, House & Senate Labor & Commerce Committees, Legislative Council, Lt. Governor, Governor, and Department of Law (Law). It is also emailed to board members and affected staff, including the commissioner's office. Public notice will be posted on the board's webpage.

Comment Period

10. The Regulations Specialist or board staff shall make a good faith effort to answer relevant questions received at least 10 days before the end of the public comment period. Questions must be in writing or asked at the legally noticed public meeting. The Regulations Specialist or board staff shall answer questions in writing and make the questions and answers available on the Alaska Online Public Notice System and the board's webpage. FAQs will be posted on the board's webpage and updated when relevant questions are answered. The Regulations Specialist or board staff may, but are not required to, answer written questions received after the 10-day cutoff date.

11. After the comment deadline (at least 30 days in duration), comments received on proposed regulation changes are compiled and copied by the Regulations Specialist and given to board staff to include in the board packets for the next open board meeting to be considered prior to adopting. Comments received after the deadline should not be forwarded to the board and comments should not be taken at the board meeting from the public prior to adoption unless a hearing was noticed and the comments are heard by the board during the comment period.

Adoption

12. The board's options regarding the proposed regulation changes at its next meeting are:

a. It can adopt the proposed regulation changes as written/publicly noticed, amend, and adopt them; or
b. Choose to take no action on them.
c. Substantive changes may require additional drafting and public notice (**see** Step 7 above).

13. When making a motion to adopt the regulations, the board is required to state on the record that it has reviewed any comments received, and considered the cost to private persons of the regulatory action being taken.

14. When regulation changes are adopted:

a. The chair signs the adoption/certification order; and
b. The board staff signs an affidavit of board action and/or affidavit of oral hearing (if applicable) and attaches it to the relevant minutes or an excerpt of the minutes and forwards to the Regulations Specialist.

Finalizing the regulation change process

15. Regulations Specialist prepares the final regulation package for transmittal to Department of Law for final review/approval, which includes the adopted regulations, certain affidavits, and other appropriate documents.

16. Assigned agency attorney reviews the regulations.

17. Regulations attorney reviews and either approves or disapproves regulation changes. Law reviews and will occasionally make edits. (On rare occasions, this may require the edited version to be re-adopted by the board at a subsequent meeting.) At the same time, the adopted regulations are submitted to the governor for review. The governor has 30 days to review the regulations under AS 44.62.040(c), and return the regulation for specified reasons.

18. Unless returned by the governor, when the governor and Law's review are complete, the adopted regulations are forwarded to the Lt. Governor for filing. Regulation changes are effective 30 days after filing unless a later effective date is specified in the adoption order.

Once regulations are effective

19. Agency posts summary of approved regulation changes on Alaska Online Public Notice System.

20. Agency updates statutes and regulations board webpage.

21. Regulation published in Alaska Administrative Code.

[1] The process may take six months to a year or longer to complete. It may be expedited if a board meets often or holds a teleconference following the written comment period to adopt the final regulations. Department of Law workload also plays a big part in the timeframe.

[2] Board minutes reflecting concisely what the project entails plays an important part in getting a project rolling. This is true for the initial stages and the final motion adopting the regulations following the public comment period due to the relevant minutes or an excerpt of the minutes being forwarded to the Department of Law with the final project.

VI. Effective Regulations

This section is intended to provide you with a general overview of the regulations process. It is not legal guidance; the applicable statutes control. Any legal questions should be addressed to the Department of Law.

Regulations must be based on statutory authority. Within the division, regulations typically clarify the requirements of the occupational licensing program as set forth by the Alaska State Legislature in statute. As mentioned in the beginning of this manual, statutes are state laws that authorize and set out the scope of a board or commission's governance authority of a licensing program. Statutes may also authorize and direct the division's management role in all licensing programs overseen by the division. Where statutes assign to a board the responsibility of adopting regulations, that board must follow the process set forth in the Administrative Procedure Act (APA) (AS 44.62.010–44.62.305) unless the legislature has by statute directed a board or commission to follow another process. The APA's requirements are explained in detail in the *Drafting Manual for Administrative Regulations.* The Drafting Manual is at http://law.alaska.gov/doclibrary/drafting_manual.html.

State agencies subject to the APA must follow the statutory procedures in order to adopt, amend, or repeal a regulation. A significant step in the APA requires that the public receive notice of a proposed regulation and an opportunity to comment on a proposed regulatory action. This ensures that the public and interested parties—predominantly licensees and prospective licensees—are aware of the proposed changes affecting their programs and provides adequate opportunity to comment on them. By ensuring public notice and ability to comment, the APA's procedures support the public's vital role in the regulations process.

Overview of the Regulations Process

When a board identifies the need to propose a regulation to implement, interpret or make specific a state statute, the board, it should begin organizing its collective thoughts on the matter, at a publicly noticed meeting. If the subject matter is highly technical or complex, it may be helpful for the board to form a working group from among its members. That group may engage in fact-finding outside of public meetings, for the purpose of sharing its findings with the entire board at an appropriate meeting.

The maker of the motion to propose amendment, adoption, or repeal of regulations should provide the board with a written draft of the proposal. It is the board's responsibility to be certain that the record reflects what the board intended. This means that the board should articulate what it is hoping to accomplish with the project, and it should carefully review written drafts, to ensure that the language conveys what the board intended. It is the board's job to provide at least the initial draft of language for a proposed regulation or amendment to regulation. Some boards find it helpful to request assistance from their staff, executive director, and the department's regulations specialist.

Under the APA, the public must have a minimum of 30 days to comment (either orally or in writing, or both) on proposed regulations. During the comment period, the staff must publish on the website answers to questions from the public on the proposed regulations received in writing unless the questions are received within 10 days before the close of the comment period; in that case the staff may, but is not required to, answer the questions. The board will meet either telephonically or in person after this period closes to review written comments and amend or adopt the proposal. A board may also notice a meeting at which oral testimony may be heard on the proposal.

If the board chooses to substantially amend its proposal, it must go out for another 30-day public comment period. Whether the amendments to the proposed regulations would require a new notice and comment period should be reviewed by the Department of Law. If the changes are minor and do not alter the meaning of the regulations, it may then be forwarded for review by the Department of Law.

The Department of Law will assign an agency attorney who is familiar with licensing issues to review the proposal for content. Once the agency attorney review is complete, either the regulations attorney or the assistant regulations attorney will review for legality, consistency with other provisions of law and conformance to the state's drafting style. If there are questions, the regulations attorneys will contact the agency attorney. Once the regulations have been approved by the regulations attorney in the Department of Law, the regulations are transmitted to the Office of the Lieutenant Governor for filing. Once signed by the Lieutenant Governor or the Lieutenant Governor's designee, his/her designee, the regulation will become effective in 30 days *unless* another effective date is specified in the adoption order or certification of adoption.

A typical board or commission regulations process can take 90-180 days, depending on the workload of the division Regulations Specialist, the complexity of the project, and scheduling a review with the Department of Law.

Due to Alaska's small population, Board members may be easily accessible to their licensees and public stakeholders. Board members must remember that comments on proposed regulations must be received as requested in the notice of proposed regulations. Comments may only be received on proposed regulations by -

Written comments that are received by the division Regulations Specialist during the public comment period as set out in the notice of proposed regulations, oral comments that are received by the board during the public comment period noticed on the state Online Public Notice System

Board members may not receive comments directly via email, text, in the grocery store, at the lodge, in the hair salon, or on the golf course. When well-meaning members of the public offers input, thank them for their interest but remind them that you are only one of several board members and the board can only act as one; therefore, they should submit their comment as directed in the public notice.

The Division Director may also draft and notice regulations through the same process, though there may not be a public meeting to deliberate or adopt final regulations. The same public notice provisions apply, and the Director must consider all written comments received. When setting fees for licensing programs, the Director will seek board input on proposed fees as required in AS 08.01.065. The Director may adopt regulations that pertain to all licensing programs in general (known as Centralized Regulations) and may adopt regulations that direct the licensing programs in AS 08.01 that do not have a governing board or commission.

Where to Seek Help

The division Regulations Specialist II is trained to assist in drafting regulations and moving them through the adoption process. The Division Director, Division Operations Manager, or Executive Administrator should also be able to walk the board through the process of adopting regulations. They may also request attorney advice independently or on behalf of the board. The flow charts that follow should clarify the processes of board and division regulation adoption, though the process is ultimately administered by the Department of Law.

Is It A Regulation Or Policy?

REGULATIONS

- Anything that affects the public or is used by the agency in dealing with the public;
- Have the force and effect of law;
- Licensees must follow them;
- Prospective licensees must comply with them in order to be licensed;
- Can only be created by following the process outlined in the Administrative Procedure Act – AS 44.62;
- This process can be time-consuming, taking months or years. It involves at a minimum:
    - 30-day public notice,
    - Review by Department of Law, and,
    - Can't be changed, except by formal process.

POLICIES, ADVISORIES, AND GUIDELINES

- Anything a regulatory boards says that:
    - Sets out the regulatory board's expectations in general, nonbinding terms,
    - Does not have the force and effect of law.

- Disciplinary Matrix is a *guideline* if it is used as a reference point, along with:

- Careful consideration of facts and circumstances, as well as,
- Underlying goals of the statute and purpose for the discipline.

- Disciplinary Matrix is a *regulation* if it is used:
  - As a formula: *"If licensee did X, then disciplinary response = Y."*
  - To achieve or demonstrate consistency by showing how the board will respond in every case where certain facts are present: *"All licensees who do X get Y."*

GENERAL PRINCIPLES APPLICABLE TO BOTH REGULATIONS AND POLICIES

- Clarity
  - If it affects licensees or the public, it should be available and understandable. *Ex.:* if the board keeps a list of activities that it will approve as uncompensated professional activities under 12 AAC 44 620((a)(2)(E), the list should be accessible on the board's website.

- Consistency
  - With other communications about similar facts;
  - With the governing statute's purpose.
  - Proportionality
    - License denials and disciplinary actions including suspension, revocations, and fines should be consistent with the statute's goals.

Steps in the Board Regulation Adoption Process

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Department of Law opens file.

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Day 45

Division publishes and distributes public notice, additional regulation notice information, and proposed regulation to all licensees and interested parties. Public notice posted in newspaper and on Alaska Online Public Notice System

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Public comment period and/or hearing (if applicable).

Day 65

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Division Regulations Specialist compiles answers to questions and posts FAQ on the program web page.

Day 75

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Day 90

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Board holds an open meeting to review public comments, make minor changes, and adopt regulations. Substantive changes may require additional drafting and public notice (Step 2).

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Division submits final regulation package to Department of Law for review and approval, and to the Governor's office.

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Day 150

.

Once Regulations Are Effective

14a

Agency posts summary on Alaska Online Public Notice System

14b

Regulation published in Alaska Administrative Code

14c

Forms & FAQ updated on program web page

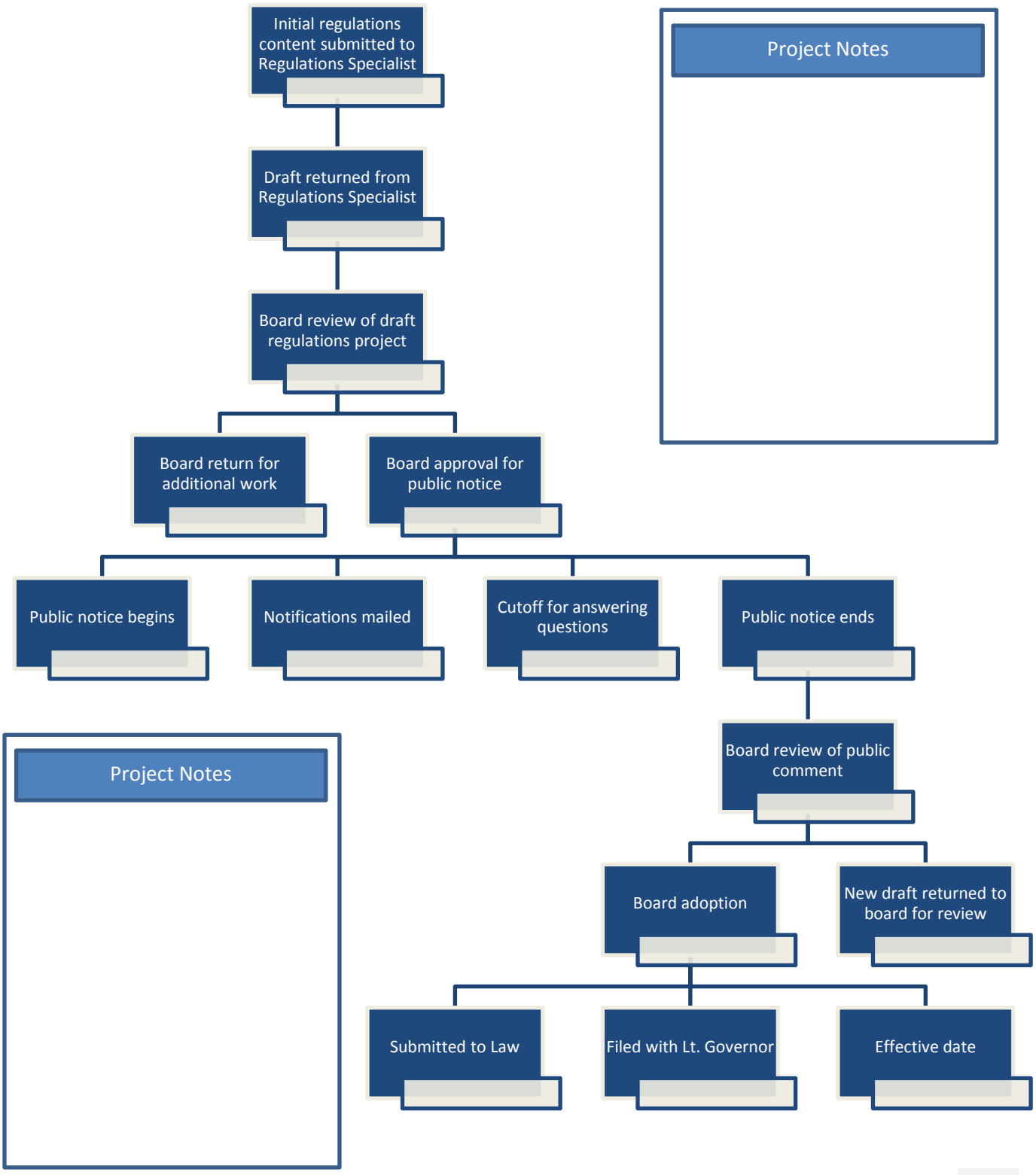
All timeframes are estimated, dependent upon staff and attorney workflow and board scheduling.

Regulations Project Tracker

☐ CBPL ☐ Board: _____

General topic of regulations: _____

Regulations being amended: 12 AAC _____



Regulation Changes Questionnaire

Division/Board: _____ Meeting Date:_____

Regulation change being proposed: 12 AAC_____

General topic of the regulation: _____

This worksheet is designed to help the board think through an anticipated regulations project. Staff will provide this worksheet to the board at the time a regulations project is being approved for public notice. This information will be used to develop a FAQ to be posted on the board's web page to help the public understand the project. Staff will submit the completed worksheet with the draft board minutes to the Regulations Specialist within 10 days of the meeting and provide a copy to the supervisor. Appropriate staff will be assigned to complete this worksheet if a division regulation. **NOTE:** ***Use a separate worksheet for each section being proposed.***

1. Is the new regulation needed to comply with new legislation or federal law?	Yes ☐ No ☐
If yes, effective date of new statute/federal law: _____	
(If appropriate, ensure the new regulation is in line with federal requirements prior to initiating a regulation project.)	
2. Does the change add a new license type?	Yes ☐ No ☐
If yes:	
Does it affect current licensees?	Yes ☐ No ☐
Do current licensees/non-licensees already perform the service for which the new license type is required?	Yes ☐ No ☐
Is there a grace period or date explicitly included in the regulation to allow for a transition period?	Yes ☐ No ☐
3. Does it change the qualifications or requirements of an existing license?	Yes ☐ No ☐
If yes, does it affect current licensees?	Yes ☐ No ☐
4. Does it affect continuing education/competency requirements?	Yes ☐ No ☐
If yes:	
Does it add additional requirements or hours?	Yes ☐ No ☐
Does it clarify existing regulations?	Yes ☐ No ☐
Is there an effective date in the future to give licensees time to comply?	Yes ☐ No ☐
5. Is it a fee change or does it create a new fee?	Yes ☐ No ☐
If yes:	
Does it move fees in the centralized regulations to a new number, therefore affecting other program regulations?	Yes ☐ No ☐
6. Does it make changes to the requirements of licensees?	Yes ☐ No ☐
If yes:	
All licensees	Yes ☐ No ☐
Certain licensees (List: _____)	Yes ☐ No ☐
Initial licensees	Yes ☐ No ☐
7. In addition to interested parties, who should receive the public notice? (All licensees or certain license types?)	

8. In addition to the 30-day minimum written notice, does the board request a public hearing? If yes, when and where.
9. What will the regulation do?
10. What is the demonstrated public need or purpose of this regulation?
11. What is the known or estimated cost of the new regulation to a private person, another agency, or a municipality (see Step 3 of the *Steps in the Regulation Process…*)?
12. What positive consequences may this regulation have on public or private people, businesses, or organizations?
13. What negative consequences may this regulation have on public or private people, business, or organizations?
14. If any negative consequences, please address the reasons why the public need for this change outweighs the negative impact.
15. List any additional questions or comments that may arise from the public during the comment period. Include a response to the questions.
16. What type of notification outlining the changes will be required once the regulation is adopted? Check appropriate boxes. FAQ on website ☐ Email to licensees ☐ *Letter to licensees ☐ * *Cost to board for mailing letter*

Staff submitting this worksheet: _____ Date submitted to Regulations Specialist: _____

12 AAC 52.855. Registration With the Prescription Drug Monitoring Program [CONTROLLED SUBSTANCE PRESCRIPTION DATABASE.]

…..

(b) [IF NOT DISPENSING IN THIS STATE, A PHARMACIST SHALL SUBMIT, NOT LATER THAN 30 DAYS AFTER INITIAL LICENSURE, A PDMP DISPENSATION EXEMPTION FORM PROVIDED BY THE BOARD.] A pharmacist who [SUBMITTED A DISPENSATION EXEMPTION FORM] **who was not dispensing at the time of initial licensure but plans to begin dispensing** shall register with the PDMP before dispensing a schedule II, III, or IV controlled substance under federal law in this state.

…

[(f) A PHARMACIST OR PRACTITIONER REQUIRED TO REGISTER WITH THE PDMP MAY ACCESS INFORMATION IN THE PDMP USING ANOTHER REGISTRANT'S CREDENTIALS ONLY AS AUTHORIZED BY A CONTRACT EXECUTED BY THE DEPARTMENT FOR THE PURPOSES OF AS 47.05.270.]

12 AAC 52.860. Access to and Conditions for Use of the Prescription Drug Monitoring Program [DATABASE].

…..

12 AAC 52.865. Reporting and Reviewing PDMP information.

…..

(a) Unless excused from reporting under AS 17.30.200(t), a **pharmacist-in-charge** [PHARMACIST] must submit information **on behalf of the employing pharmacy** required under AS 17.30.200(b) **and other details required by the American Society of Automation in Pharmacy (ASAP)**, if the pharmacist-in-charge is not present**, a pharmacist or third-party vendor may report on behalf of the pharmacy. A practitioner, practitioner's delegate, or third-party vendor may also report on behalf of the practitioner**.

(b) Unless excused from reporting under AS 17.30.200(t), a pharmacist or practitioner

Commented [CLN(1]: Modernize title.

Commented [CLN(2]: This conflicts with our current MOU with the HIE. The HIE is unable to provide us with an audit report for when providers review patients via their medical director's credentials. We signed off on the MOU on the assurance that an audit trail would be available upon request so we can meaningfully track mandatory use and ensure security.

Commented [CLN(3]: Modernize

required to submit information under AS 17.30.200(b) must submit the information to the PDMP daily [AS OF THE PREVIOUS SUBMISSION DATE].

(c) **If the pharmacist or practitioner did not dispense any Schedule II, III, or IV controlled substances on the previous day, the pharmacist or practitioner must submit a zero report.**

(d) The time computation under 12 AAC 02.920(b) applies to a submission of information under AS 17.30.200(b) and this section.

(e) [(d)] For the purposes of AS 17.30.200(b)(1), "other appropriate identifier" and for the purposes of 17.30.200(b)(8), "other appropriate identifying information" mean the state-issued license number of the prescribing practitioner and state-issued license number of the dispensing pharmacist or practitioner.

(f) [(e)] Not later than 72 hours after discovering an error in information submitted under AS 17.30.200(b), a pharmacist or practitioner required to submit the information under AS 17.30.200(b) must [SUBMIT INFORMATION CORRECTING THE ERROR TO] **notify** the PDMP administrator. The time computation under 12 AAC 02.920(b) applies to a submission of information correcting an error in information submitted under AS 17.30.200(b).

(g) [(f)] Unless excused from reporting under AS 17.30.200(t), or a waiver is granted under 12 AAC 52.870, a pharmacist or practitioner required to submit information under AS 17.30.200(b) must submit the information to the PDMP electronically through the website provided by the board.

(h) To submit data for an animal prescription, a pharmacist or veterinarian must report

(1) the first name of the animal;

(2) last name of the owner;

(3) date of birth of the owner;

(4) species of the animal;

(5) address of the owner;

(6) name, quantity, and dose of the drug; and

(7) other details required by ASAP standards, including the correct species code, PAT 02.

(i) Unless excused from reviewing the PDMP under AS 17.30.200(k)(4)(A) – (B), a practitioner, but not a pharmacist, must review the information in the PDMP to check a patient's prescription records before dispensing, prescribing, or administering a schedule II or III controlled substance under federal law.

(j) A veterinarian required to review the PDMP under AS 17.30.200(k) satisfies this requirement by reviewing data pertaining to the animal's owner. For the purpose of this section, "owner" means the client identified in 12 AAC 68.100 and defined in 12 AAC 68.990.

Commented [4]: What is this?

Commented [5]: Patient = 02 "PAT 02" means it is a prescription for an animal as opposed to a human, which is coded as "PAT 01"

Commented [6R5]: Consider removing this and stopping at correct species code. What happens if this changes?

Commented [7]: Is this correct?

Commented [8]: Maybe should be "as described in 12 AAC 68.990(1)"? This is the definition for "client"

12 AAC 52.423. Remote Pharmacy License.

….

(a) A central pharmacy that wishes to provide pharmacy services through a remote pharmacy in the state using a telepharmacy system as provided in 12 AAC 52.425 must apply to the board for a license. The central pharmacy applying under this section must submit to the department

(1) a complete, notarized application on a form provided by the department;

(2) the applicable fees established in 12AAC 02.310; and

(3) comply with the requirements of 12 AAC 52.020.

(b) The board will approve an application to provide pharmacy services through a remote pharmacy if the central pharmacy establishes that [(1)] it is able to comply with the requirements

of 12 AAC 52.425[; AND (2) THERE IS NO ACCESS TO A NON-REMOTE PHARMACY WITHIN TEN ROAD MILES OF THE PROPOSED REMOTE PHARMACY SITE UNLESS THE NON-REMOTE PHARMACY IS PREVENTED BY FEDERAL LAW FROM PROVIDING PHARMACY SERVICES TO ALL THE INDIVIDUALS WITHIN THE TEN ROAD MILES].

(c) A remote pharmacy that has changed its name, physical address, or ownership must notify the board on a form provided by the department within 30 days of the change. If a change of physical address, the notification must include an attestation that a new inspection will be completed within 30 days of commencement of business.

(d) An applicant for renewal of a remote pharmacy license must comply with the requirements of 12 AAC 52.300.

12 AAC 52.800. Drug room license.

Commented [CLN(9]: Conforming change with other section amendments

….

(c) A drug room that has changed its name, physical address, or ownership must notify the board in writing within 30 days of the change. The notification must include an attestation that a new inspection will be completed within 30 days of commencement of business.

(d) An applicant for renewal of a drug room license must comply with the requirements of 12 AAC 52.300.

12 AAC 52.NEW. Automated Distribution Kiosks.

….

(a) A licensed pharmacy in this state may install and use automated drug distribution kiosks which are accessible to the patient or the patient's agent, while the pharmacy is open or closed, for the purpose of purchasing their completed prescription drug orders if

(1) the kiosk is securely installed within 10-feet of the licensed pharmacy and is properly secured to prevent easy removal. The kiosk may be

(A) bolted to the floor;

(B) framed into the wall; or

(C) secured in any other physical means which prevents easy removal;

(2) prior to the completed prescription drug order being loaded into the kiosk, the pharmacist has counseled the patient in accordance with 12 AAC 52.230; and

(3) no drugs that are a controlled substance as defined by state or federal law are placed in the kiosk and there is a conspicuously posted sign on the machine which states "this machine does not contain controlled substances".

(4) the sign must use a minimum of size 72 font and red color;

(b) The pharmacist on duty is responsible for

(1) assigning, discontinuing, or modifying access to the system by pharmacy technicians or pharmacist interns; and

(2) ensuring proper maintenance of the kiosk.

(c) This section does not apply to

(1) prescription drug dispensing or distribution machines used in institutional facilities; or

(2) other professional practices in accordance with AS 08.80.400.

(d) In AS 08.80, "automated distribution kiosks" means a vending machine that stores and distributes prescription drugs or devices, and maintains a record of transactions initiated or completed.

12 AAC 52.420. Security.

…..

(c) Excluding prescription drugs or devices held within an automated distribution kiosk, all drugs, devices, and other items or products that are restricted to sale by or under the direct supervision of a pharmacist shall be kept in the prescription department.

(d) Excluding prescription drugs or devices held within an automated distribution kiosk, the prescription department shall be secured to prevent unauthorized access when a pharmacist is not available to provide direct supervision.

(f) Excluding prescription drugs or devices held within an automated distribution kiosk, prescriptions shall be stored in the prescription department and may be removed only under the direct supervision of a pharmacist and for immediate delivery to the patient, the patient's agent, or the person delivering the prescription to the patient or the patient's agent.

12 AAC 52.010. Classification of licensure.

….

(b) The board will issue the following categories of licenses or registrations to a qualified facility:

….

(7) third-party logistics provider license **located outside of the state**;

(8) outsourcing facility license **located outside of the state**;

(10) manufacturer located outside of the state.

Commented [CLN(10]: Aligns with (5) and (9) since the board only has authority to regulate these facilities if outside of Alaska.

12 AAC 52.300. License and registration renewal

….

12 AAC 52.300. License and registration renewal. (a) Pharmacy, remote pharmacy, wholesale drug distributor, outsourcing facility, third-party logistics provider, **manufacturer**, pharmacist, pharmacy technician, and drug room licenses must be renewed biennially on or before a date set by the department.

Commented [CLN(11]: To include out-of-state pharmacies

….

(d) [A PHARMACY THAT HAS CHANGED ITS NAME, PHYSICAL ADDRESS, OR OWNERSHIP SINCE THE DATE IT WAS FIRST ISSUED OR LAST RENEWED IS NOT ELIGIBLE FOR RENEWAL.

(e) A WHOLESALE DRUG DISTRIBUTOR THAT HAS CHANGED ITS NAME, PHYSICAL ADDRESS, OWNERSHIP, OR FACILITY MANAGER IS NOT ELIGIBLE FOR RENEWAL IF THE CHANGE OCCURRED 30 DAYS AFTER THE DATE A RENEWAL APPLICATION IS SUBMITTED TO THE BOARD.

(f) AN OUTSOURCING FACILITY OR THIRD-PARTY LOGISTICS PROVIDER THAT HAS CHANGED ITS NAME, PHYSICAL ADDRESS, OWNERSHIP, OR FACILITY MANAGER IS NOT ELIGIBLE FOR RENEWAL.

(e) A WHOLESALE DRUG DISTRIBUTOR THAT HAS CHANGED ITS NAME, PHYSICAL ADDRESS, OWNERSHIP, OR FACILITY MANAGER IS NOT ELIGIBLE FOR RENEWAL IF THE CHANGE OCCURRED 30 DAYS AFTER THE DATE A RENEWAL APPLICATION IS SUBMITTED TO THE BOARD.

(f) AN OUTSOURCING FACILITY OR THIRD-PARTY LOGISTICS PROVIDER THAT HAS CHANGED ITS NAME, PHYSICAL ADDRESS, OWNERSHIP, OR FACILITY

MANAGER IS NOT ELIGIBLE FOR RENEWAL.]

12 AAC 52.920(a). Disciplinary guidelines.

….

(14) for the following licensees, failing to establish or maintain effective controls against the diversion or loss of prescription drugs or prescription drug records, or failing to ensure that prescription drugs are dispensed in compliance with state and federal laws and regulations:

(A) a pharmacist-in-charge of a pharmacy, **to the extent the pharmacist-in-charge is licensed under this chapter**;

(B) a designated representative of a wholesale drug distributor, outsourcing facility, third-party logistics provider, or manufacturer, to the extent the designated representative is licensed under this chapter;

~~(B)~~**(C)** a sole proprietor or individual owner of a pharmacy, **to the extent the sole proprietor or individual owner is licensed under this chapter**;

~~(C)~~**(D)** a partner in the ownership of a pharmacy **to the extent the partner is licensed under this chapter**; or

~~(D)~~**(E)** a managing officer of a corporation, association, or joint-stock company owning a pharmacy, **to the extent the managing officer is licensed under this chapter**;

12 AAC 52.995. Definitions.

….

(a) In this chapter, unless the context requires otherwise,

…. **(39) "manufacturer" means a person or entity, including a virtual manufacturer, engaged in the manufacturing of drugs or devices. A manufacturer which distributes its own manufactured drugs or devices does not constitute wholesale drug distribution. To manufacture also does not include the distribution of minimal quantities of a drug by a licensed retail pharmacy to a licensed practitioner for office use.**

(40) "virtual manufacturer" means a manufacturer that sells a prescription drug or device but never physically possesses the product.

….

(e) In 12 AAC 52.610 – 12 AAC 52.697, "[FACILITY MANAGER] **designated representative**" means the responsible manager who serves as the supervisor or manager and is

Commented [CLN(12]: Per LAW's May 10, 2022 guidance.

Commented [CLN(13]: From NABP model act and legal guidance from Megyn.

Commented [CLN(14]: Will need to be adjusted to include the regulation for manufacturer licensing.

responsible for ensuring the third-party logistics provider, wholesale drug distributor, [OR] outsourcing facility, **or manufacturer** is in compliance with all state and federal laws and regulations pertaining to the operations.

12 AAC 52.635. [FACILITY MANAGER] **Designated representative.**

Commented [CLN(15]: Aligns with recognized industry term; see NABP model act

….

(a) a [FACILITY MANAGER] **designated representative** of a wholesale drug distributor, outsourcing facility, [OR] third-party logistics provider, **or manufacturer** designated to replace the [FACILITY MANAGER] **designated representative** of a facility shall notify the board within [10] **30** days of that designation, by submitting a completed change of [FACILITY MANAGER] **designated representative** notice **in writing** [ON A FORM PROVIDED BY THE DEPARTMENT]. The outgoing [FACILITY MANAGER] **designated representative** shall also notify the board **in writing** within [10] **30** days [ON A FORM PROVIDED BY THE DEPARTMENT.]

(b) a [FACILITY MANAGER] **designated representative** may be in charge of more than one location and may be designated as the [FACILITY MANAGER] **designated representative** for multiple facilities simultaneously.

12 AAC 52.NEW. Manufacturer license.

Commented [CLN(16]: Required license type per AS 08.80.480(17); board must create regulations.

12 AAC 52.NEW. Manufacturer. (a) An out-of-state applicant for a manufacturer license shall submit the requirements in (b) of this section for review and approval by the executive administrator. An application that does not clearly demonstrate qualifications for licensure must be reviewed and approved by the board.

(b) The board will issue a manufacturer license to an applicant who

(1) submits a completed application on a form provided by the department;

(2) pays the applicable fees required in 12 AAC 02.310;

(3) provides the name of the designated representative who will manage the manufacture of drugs or devices for the wholesale drug facility;

(4) submits an attestation that

(A) a self-inspection of the premises using the form provided by the department was completed within the last two years; or

(B) an inspection of the premise by a third-party was completed within the last two years;

(5) submits an attestation that it holds a license as a manufacturer in another jurisdiction and that the license is in good standing;

(c) A manufacturer operating as a virtual manufacturer must indicate on the application that it operates as a virtual manufacturer that meets the definition of 12 AAC 52.995.

(d) A manufacturer that has changed its name, physical address, or ownership must notify the board in writing within 30 days of the change. If a change of physical address, the notification must include an attestation that a new inspection will be completed within 30 days of commencement of business.

(e) When a manufacturer ceases operations, the designated representative of the wholesale drug distributor shall notify the board in writing of the cessation of operations; the form must be submitted within [10] **(30)** days after the cessation of operations.

(f) a manufacturer that distributes drugs and devices it does not directly manufacturer must hold a separate wholesale drug distributor license.

(g) a manufacturer that provides logistics services must hold a separate third-party logistics provider license.

12 AAC 52.610. Wholesale drug distributor license.

….

Commented [CLN(17]: Conforming changes to update terminology/introduction of manufacturer section.

(b) The board will issue a wholesale drug distributor license to an applicant who

(1) submits a completed application on a form provided by the department;

(2) pays the applicable fees required in 12 AAC 02.310;

(3) provides the name of the [FACILITY MANAGER] **designated representative** who will manage the wholesale distribution of drugs or devices for the wholesale drug facility;

Commented [CLN(18]: Aligns with recognized industry term; see NABP model act

(c) [WITHIN 30 DAYS AFTER A CHANGE IN] **A wholesale drug distributor that has changed its name,** physical address, **or** ownership[, OR NAME, THE WHOLESALE DRUG DISTRIBUTOR] **must** [APPLY FOR A NEW AND SEPARATE WHOLESALE DRUG DISTRIBUTOR LICENSE IN ACCORDANCE WITH THIS SECTION] **notify the board in writing within 30 days of the change. If a change of physical address, the notification must include an attestation that a new inspection will be completed within 30 days of commencement of business.**

~~(c)~~**(d)** When a wholesale drug distributor ceases operations, the [FACILITY MANAGER] **designated representative** of the wholesale drug distributor shall notify the board **in writing** [ON A FORM PROVIDED BY THE DEPARTMENT] of the cessation of operations; the form must be submitted within [10] **(30)** days after the cessation of operations.

12 AAC 52.696. Outsourcing facilities

….

12 AAC 52.696. Outsourcing facilities. (a) An **out-of-state** applicant for an outsourcing facility license shall submit the requirements in (b) of this section for review and approval by the executive administrator. An application that does not clearly demonstrate qualifications for licensure must be reviewed and approved by the board.

Commented [CLN(19]: Because the board can only regulate outsourcing facilities located outside of Alaska per AS 08.80.157(k) and AS 08.80.159.

(b) The board will issue an outsourcing facility license to an applicant who

(1) submits a complete application on a form provided by the department;

(2) pays the applicable fees required in 12 AAC 02.310;

(3) provides the name of the designated [FACILITY MANAGER] **representative**;

(4) submits an attestation that it holds a license as an outsourcing facility in another jurisdiction and that the license is in good standing;

~~(4)~~ **(5)** submits an attestation that a self-inspection of the premises using the form provided by the department was completed within the last two years; and

~~(5)~~ **(6)** submits the results of the most recent Good Manufacturing Practice (GMP) inspection by the United States Food and Drug Administration.

(c) [WITHIN 30 DAYS AFTER A CHANGE IN] **An outsourcing facility that has changed its** physical address **or** ownership [THE OUTSOURCING FACILITY] **must** [APPLY FOR A NEW AND SEPARATE OUTSOURCING FACILITY LICENSE IN ACCORDANCE WITH THIS SECTION] **notify the board in writing within 30 days of the change. The notification must include an attestation that a new inspection will be completed within 30 days of commencement of business.**

(e) When an outsourcing facility ceases operations, the [FACILITY MANAGER] **designated representative** must submit to the board a written notice of the cessation of operations. The written notice must be submitted within [10] **(30)** days after the cessation of operations and include

12 AAC 52.697. Third-party logistics providers

….

12 AAC 52.697. Third-party logistics providers. (a) An **out-of-state** applicant for a

Commented [CLN(20]: NABP Model Act does not address other states requiring new applications as a result of a change. This amendment will result in streamlined license processing.

Consideration for board: loss of revenue

Commented [CLN(21]: Because the board can only regulate 3PLs located outside of Alaska per AS 08.80.157(k) and AS 08.80.159.

third-party logistics provider license shall submit the requirements in (b) of this section for review and approval by the executive administrator. An application that does not clearly demonstrate qualifications for licensure must be reviewed and approved by the board.

(b) The board will issue a third-party logistics provider license to an applicant who

(1) submits a complete application on a form provided by the department;

(2) pays the fees required in 12 AAC 02.310;

(3) provides the name of the designated [FACILITY MANAGER] **representative**;

(4) submits an attestation that it holds a license as an outsourcing facility in another jurisdiction and that the license is in good standing; and

~~(4)~~ **(5)** submits an attestation that a self-inspection of the premises using the form provided by the department was completed within the last two years.

(c) [WITHIN 30 DAYS AFTER A CHANGE IN] **A third-party logistics provider that has changed its** physical address **or** ownership[, THE THIRD-PARTY LOGISTICS PROVIDER] **must** [APPLY FOR A NEW AND SEPARATE THIRD-PARTY LOGISTICS PROVIDER LICENSE IN ACCORDANCE WITH THIS SECTION] **notify the board in writing within 30 days of the change. The notification must include an attestation that a new inspection will be completed within 30 days of commencement of business.**

(d) When a third-party logistics provider ceases operations, the [FACILITY MANAGER] **designated representative** must submit to the board a written notice of the cessation of operations. The written notice must be submitted within [10] **(30)** days after the cessation of operations and include

Commented [CLN(22]: NABP Model Act does not address other states requiring new applications as a result of a change. This amendment will result in streamlined license processing.

Consideration for board: loss of revenue

12 AAC 52.020. Pharmacy license

Commented [CLN(23]: Per Megyn/proposed rules

….

(f) A pharmacy that has changed its name, ownership, or physical address shall [APPLY FOR A NEW AND SEPARATE LICENSE IN ACCORDANCE WITH THIS SECTION] **notify the board in writing within 30 days of the change. If a change of physical address, the notification must include an attestation that a new inspection will be completed within 30 days of commencement of business.**

(g) If a retail pharmacy sells prescription drugs to licensed practitioners for office use exceeds 5 percent of the total dollar volume of the pharmacy's annual prescription drug sales, the retail pharmacy must hold a separate wholesale drug distributor license.

(h) a pharmacy located outside of the state is not required to submit an annual information update required in AS 08.80.158 to the board if the registration has been issued for less than 3 months and if the information has not changed since the registration was initially issued.

12 AAC 52.250. Job shadowing in pharmacy

Commented [CLN(24]: Repeal in its entirety; the board does not regulate any aspect of job shadowing.

[(a) A PHARMACIST-IN-CHARGE OR JOB SHADOWING PRECEPTOR OF A PHARMACY MAY ALLOW JOB SHADOWING BY A STUDENT IN THE PHARMACY ONLY AS SPECIFIED IN THIS SECTION.

(b) BEFORE A STUDENT BEGINS A JOB SHADOWING PROGRAM UNDER THIS SECTION, THE PHARMACIST-IN-CHARGE OR JOB SHADOWING PRECEPTOR SHALL COMPLETE THAT PORTION OF THE JOB SHADOWING DOCUMENTATION FORM PRESCRIBED BY THE BOARD, WHICH INCLUDES THE NAMES OF THE PHARMACY, THE PARTICIPATING STUDENT, AND THE PHARMACIST-IN-CHARGE OR JOB

SHADOWING PRECEPTOR. THE STUDENT AND THE PHARMACIST-IN-CHARGE OR PRECEPTOR, SHALL SIGN THE FORM. THE PARENT OR GUARDIAN OF THE STUDENT SHALL ALSO SIGN THE FORM IF THE STUDENT IS LESS THAN 18 YEARS OF AGE.

(c) THE PHARMACIST-IN-CHARGE OR, IF APPLICABLE, THE JOB SHADOWING PRECEPTOR SHALL FAMILIARIZE THE STUDENT WITH THE CONFIDENTIALITY REQUIREMENTS OF 45 C.F.R., PARTS 160 AND 164 (HIPAA) AND ENSURE COMPLIANCE WITH THIS SECTION AND THE RELEVANT SECTIONS OF AS 08.80 AND THIS CHAPTER.

(d) A PHARMACIST-IN-CHARGE OR JOB SHADOWING PRECEPTOR MAY NOT ALLOW

(1) A STUDENT IN A JOB SHADOWING PROGRAM TO

(A) RECEIVE ANY REMUNERATION OR OTHER COMPENSATION;

(B) PERFORM JOB SHADOWING FOR MORE THAN 50 HOURS;

(C) PERFORM ANY FUNCTIONS RESERVED FOR LICENSED, CERTIFIED, OR REGISTERED PHARMACY PERSONNEL;

(2) A RATIO OF JOB SHADOWING STUDENT TO PHARMACIST-IN-CHARGE OR JOB SHADOWING PRECEPTOR OTHER THAN ONE TO ONE.

(e) AFTER COMPLETION OF THE JOB SHADOWING PROGRAM BY A STUDENT, THE PHARMACIST-IN-CHARGE OR JOB SHADOWING PRECEPTOR SHALL COMPLETE THAT PORTION OF THE JOB SHADOWING DOCUMENTATION FORM PRESCRIBED BY THE BOARD WHERE THE PHARMACIST-IN-CHARGE OR JOB

SHADOWING PRECEPTOR PROVIDES THE DATE AND TIME IN HOURS STUDENT WAS PRESENT AND JOB SHADOWING IN THE PHARMACY, ANY PATIENT COUNSELING OBSERVATIONS, PROBLEMS THAT MAY HAVE OCCURRED DURING JOB SHADOWING. THE JOB SHADOWING DOCUMENTATION FORM MUST BE KEPT IN THE PHARMACY RECORD FOR AT LEAST TWO YEARS AFTER THE JOB SHADOWING PROGRAM HAS BEEN COMPLETED BY THAT STUDENT.

(f) IN THIS SECTION,

(1) "JOB SHADOWING" MEANS FOR EDUCATIONAL PURPOSES AND THROUGH OBSERVATION ONLY, THE OBSERVATION BY A STUDENT OF THE FUNCTIONS AND DUTIES OF A PHARMACY AND PHARMACY STAFF WITH THE INTENDED PURPOSE OF GIVING THE STUDENT AN OPPORTUNITY TO OBSERVE CAREER POSSIBILITIES AVAILABLE IN THE FIELD OF PHARMACY;

(2) "JOB SHADOWING PRECEPTOR" MEANS A LICENSED PHARMACIST, OTHER THAN THE PHARMACIST-IN-CHARGE, DESIGNATED BY THE PHARMACIST-IN-CHARGE TO SUPERVISE A STUDENT WHILE THAT STUDENT IS JOB SHADOWING;

(3) "STUDENT" MEANS A PERSON CURRENTLY ENROLLED IN A HIGH SCHOOL OR POST-SECONDARY EDUCATION PROGRAM.]

12 AAC 52.670. Drug recalls

Commented [CLN(25]: Recommend repeal; drug recalls are regulated by the FDA

[12 AAC 52.670. DRUG RECALLS. A WHOLESALE DRUG DISTRIBUTOR SHALL PREPARE AND FOLLOW

WRITTEN POLICY FOR HANDLING THE RECALL OF A DRUG DUE TO

(1) A VOLUNTARY ACTION ON THE PART OF THE MANUFACTURER;

(2) AN ORDER OF THE FOOD AND DRUG ADMINISTRATION, OR OF ANY OTHER FEDERAL, STATE, OR LOCAL GOVERNMENT AGENCY; OR

(3) THE REPLACEMENT OF AN EXISTING DRUG WITH AN IMPROVED DRUG OR NEW PACKAGE DESIGN.]

12 AAC 52.220. Pharmacist interns

….

[(d) A PHARMACIST INTERN SHALL FILE WITH THE BOARD A REPORT OF WORK EXPERIENCE ON A FORM PROVIDED BY THE DEPARTMENT WITHIN 30 DAYS OF COMPLETION OR TERMINATION OF AN INTERNSHIP IN THE PRACTICE OF PHARMACY REQUIRED UNDER 12 AAC 52.080.]

Commented [CLN(26]: Recommend repeal; pharmacist interns applying for a permanent pharmacist license must provide verification of internship or work experience anyway.

12 AAC 52.NEW. Remodeling

….

Within 30 days of undergoing structural remodeling of a pharmacy or a prescription department within the premises of a licensed or registered pharmacy that would result in a change in layout, square footage, plumbing, or additional storage areas, the licensee or registrant shall notify the board in writing. The notification must include

(a) a brief description of the remodel;

Commented [CLN(27]: Adapted from Nevada remodeling admin code, § 639.535:

https://casetext.com/regulation/nevada-administrative-code/chapter-639-pharmacists-and-pharmacy/pharmacies-in-general/section-639535-remodeling-or-relocation-of-pharmacy-or-prescription-department

And adapted from Oklahoma:

https://www.ok.gov/pharmacy/documents/DRAFT_Chapter%2015_20171228.pdf

(b) whether the remodel is to comply with USP 795, 797, or 800;

(c) an anticipated timeline of when the remodel will be complete;

(d) an attestation from the pharmacist-in-charge that a new inspection will be complete within 30 days of commencement of business following the remodel.

12 AAC 52.120. Review of pharmacist intern license application

….

(e) A pharmacist intern license supersedes a pharmacy technician license [AND THE PHARMACY TECHNICIAN LICENSE SHALL BE RETURNED TO THE BOARD]. **A pharmacy technician who obtains a pharmacist intern license under this chapter may submit a request to the board in writing to voluntarily expire the pharmacy technician license. A voluntary expiration of pharmacy technician licensure is considered a non-disciplinary relinquishment of the ability to practice under that license.**

12 AAC 52.53. RETURN OR EXCHANGE OF DRUGS.

….

(b)(2) in the pharmacist's professional judgment, the unit dose package or multiple dose medication card meets the **current** standards of the United States Pharmacopoeia **(USP)** [(1995 REVISION)] for storage conditions, including temperature, light sensitivity, and chemical and physical stability;

12 AAC 52.NEW. Adoption of United States Pharmacopeia Chapters

Commented [CLN(28]: Thoughts on a new section like this? The wording isn't a suggested recommendation for the chapters to adopt, just an example of what it could look like.

(a) The board adopts the following USP standards

(1) USP Chapter 795 concerning pharmacy compounding of non-sterile preparations;

(2) USP Chapter 797 concerning sterile preparations;

(3) USP Chapter 800 concerning handling of hazardous drugs

(4) USP Chapter 825 concerning preparation, compounding, dispensing, and repackaging of radiopharmaceuticals;

(b) Nothing prohibits a pharmacist from engaging in practice standards under chapters not adopted by reference in this section.

12 AAC 52.440. GUDIELINES RELATING TO COMPOUNDING PRACTICES.

12 AAC 52.440. GUIDELINES RELATING TO COMPOUNDING PRACTICES. A pharmacy or pharmacist that compounds drugs shall adhere to the guidelines established by the board in the pamphlet titled, "Compounding Practices," dated February 2008, and incorporated by reference in this section.

Authority: AS 08.80.030 AS 08.80.157

[EDITOR'S NOTE: THE PAMPHLET INCORPORATED BY REFERENCE IN 12 AAC 52.440, "COMPOUNDING PRACTICES" MAY BE OBTAINED FROM THE DEPARTMENT OF COMMERCE, COMMUNITY, AND ECONOMIC DEVELOPMENT, DIVISION OF CORPORATIONS, BUSINESS AND PROFESSIONAL LICENSING, BOARD OF PHARMACY, STATE OFFICE BUILDING, 9TH FLOOR, 333 WILLOUGHBY AVENUE, JUNEAU, ALASKA 99801; PHONE (907) 465-2589.]]

Commented [CLN(29]: What I'm trying to get at here is avoiding the negative implication canon, if that is an issue?

Commented [CLN(30]: Thoughts about repealing this section if the board creates a new section for USP chapters per above?

Commented [CLN(31]: Remove this entirely; the compounding practices document is already amended to the statutes and regulations booklet and that phone number belongs to our new PDMP project assistant.

12 AAC 52.443. Approval for shared pharmacy services

[(a) A REQUESTING PHARMACY IN THIS STATE THAT SEEKS TO PARTICIPATE IN SHARED PHARMACY SERVICES MUST APPLY TO THE BOARD FOR APPROVAL ON A FORM PROVIDED BY THE DEPARTMENT. (B) THE BOARD WILL APPROVE AN APPLICATION BY A REQUESTING PHARMACY TO PARTICIPATE IN SHARED PHARMACY SERVICES IF THE PHARMACY ESTABLISHES

(1) THAT THE PHARMACY HAS A CURRENT IN-STATE PHARMACY LICENSE ISSUED UNDER AS 08.80.157 AND THIS CHAPTER;

(2) THAT THE PHARMACY IS ABLE TO COMPLY WITH THE REQUIREMENTS OF 12 AAC 52.445;

(3) THAT THE PHARMACY EITHER

(A) IS OWNED BY THE SAME OWNER AS THE FILLING PHARMACY WITH WHICH PHARMACY SERVICES ARE TO BE SHARED; OR

(B) HAS A WRITTEN CONTRACT OR AGREEMENT WITH THE FILLING PHARMACY OR FILLING PHARMACIST THAT OUTLINES THE PHARMACY SERVICES TO BE PROVIDED AND THE OBLIGATION OF EACH PHARMACY OR PHARMACIST TO COMPLY WITH FEDERAL AND STATE PHARMACY STATUTES AND REGULATIONS; AND (4) THAT THE PARTICIPANTS IN SHARED PHARMACY SERVICES SHARE A COMMON ELECTRONIC FILE OR OTHER APPROPRIATE TECHNOLOGY THAT ALLOWS ACCESS TO THE INFORMATION NEEDED TO PROVIDE SHARED PHARMACY SERVICES IN COMPLIANCE WITH THE REQUIREMENTS OF AS 08.80 AND THIS CHAPTER.]

Authority: AS 08.80.005 AS 08.80.030 AS 08.80.157

12 AAC 52.443. Approval for Shared Pharmacy Services by Pharmacist

[(a) A REQUESTING PHARMACIST IN THIS STATE THAT SEEKS TO PARTICIPATE IN SHARED PHARMACY SERVICES MUST APPLY TO THE BOARD FOR APPROVAL ON

A FORM PROVIDED BY THE DEPARTMENT.

(b) THE BOARD WILL APPROVE AN APPLICATION BY A REQUESTING PHARMACIST TO PARTICIPATE IN SHARED PHARMACY SERVICES IF THE REQUESTING PHARMACIST ESTABLISHES

(1) THAT THE PHARMACIST

(A) HAS A CURRENT IN-STATE PHARMACY LICENSE ISSUED UNDER AS 08.80 AND THIS CHAPTER;

(B) HAS A WRITTEN CONTRACT OR AGREEMENT WITH THE FILLING PHARMACY OR FILLING PHARMACIST THAT OUTLINES THE PHARMACY SERVICES TO BE PROVIDED AND THE OBLIGATIONS OF EACH PHARMACY OR PHARMACIST TO COMPLY WITH FEDERAL AND STATE PHARMACY STATUTES AND REGULATIONS; AND

(C) IS ABLE TO COMPLY WITH THE REQUIREMENTS OF 12 AAC 52.445; AND

(2) THAT THE PARTICIPANTS IN SHARED PHARMACY SERVICES SHARE A COMMON ELECTRONIC FILE OR OTHER APPROPRIATE TECHNOLOGY THAT ALLOWS ACCESS TO THE INFORMATION NEEDED TO PROVIDE SHARED PHARMACY SERVICES IN COMPLIANCE WITH THE REQUIREMENTS OF AS 08.80 AND THIS CHAPTER.

Authority: AS 08.80.005 AS 08.80.030

12 AAC 52.445. Shared Pharmacy Services

(a) A PHARMACY PARTICIPATING IN SHARED PHARMACY SERVICES, OR A PHARMACIST ACTING INDEPENDENTLY OF A PHARMACY AND PARTICIPATING IN SHARED PHARMACY SERVICES, SHALL USE AN IDENTIFIER ON THE PRESCRIPTION CONTAINER THAT IDENTIFIES PRESCRIPTIONS TO BE FILLED AT A FILLING PHARMACY OR BY THE FILLING PHARMACIST. THE REQUESTING PHARMACY OR REQUESTING PHARMACIST SHALL NOTIFY THE PATIENT OR THE

PATIENT'S AGENT THAT THE PATIENT'S PRESCRIPTION ORDER MAY BE PROCESSED OR FILLED BY ANOTHER PHARMACY OR PHARMACIST, AND SHALL IDENTIFY THE FILLING PHARMACY OR FILLING PHARMACIST. IF THE REQUESTING PHARMACY IS PART OF A NETWORK OF PHARMACIES UNDER COMMON OWNERSHIP, AND THE PRESCRIPTION ORDER MAY BE PROCESSED OR FILLED AT ANY OF THE PHARMACIES IN THE NETWORK, THE REQUESTING PHARMACY SHALL NOTIFY THE PATIENT OF THIS. NOTICE UNDER THIS SUBSECTION MAY BE PROVIDED THROUGH AN INITIAL WRITTEN NOTICE TO THE PATIENT OR THE PATIENT'S AGENT, OR THROUGH THE USE OF A SIGN PROMINENTLY DISPLAYED IN THE REQUESTING PHARMACY OR IN THE PUBLIC PORTION OF THE OFFICE OF THE REQUESTING PHARMACIST.

(b) EXCEPT AS PROVIDED IN (C) OF THIS SECTION, IF A FILLING PHARMACY OR FILLING PHARMACIST DELIVERS A PRESCRIPTION MEDICATION DIRECTLY TO THE PATIENT OR THE PATIENT'S AGENT, THE FILLING PHARMACY OR FILLING PHARMACIST SHALL PROVIDE, ON THE PRESCRIPTION CONTAINER OR ON A SEPARATE SHEET DELIVERED WITH THE PRESCRIPTION CONTAINER,

(1) THE LOCAL TELEPHONE NUMBER AND, IF APPLICABLE, THE TOLL-FREE TELEPHONE NUMBER OF THE FILLING PHARMACY OR FILLING PHARMACIST; AND

(2) A STATEMENT THAT CONVEYS TO THE PATIENT OR PATIENT'S AGENT THE FOLLOWING INFORMATION: "WRITTEN INFORMATION ABOUT THIS PRESCRIPTION HAS BEEN PROVIDED FOR YOU; PLEASE READ THIS INFORMATION BEFORE YOU TAKE THE MEDICATION. IF YOU HAVE QUESTIONS CONCERNING THIS PRESCRIPTION, A PHARMACIST IS AVAILABLE DURING NORMAL BUSINESS HOURS TO ANSWER THESE QUESTIONS AT [INSERT THE FILLING PHARMACIST OR FILLING PHARMACY'S TELEPHONE NUMBERS].

(C)THE REQUIREMENTS OF (B) OF THIS SECTION DO NOT APPLY TO PRESCRIPTION MEDICATION DELIVERED TO PATIENTS IN FACILITIES WHERE A LICENSED HEALTH CARE PROFESSIONAL IS RESPONSIBLE FOR ADMINISTERING THE PRESCRIPTION MEDICATION TO THE PATIENT.

(D) A PHARMACY PARTICIPATING IN SHARED PHARMACY SERVICES, OR A PHARMACIST ACTING INDEPENDENTLY OF A PHARMACY AND PARTICIPATING IN SHARED PHARMACY SERVICES, SHALL

(1) MAINTAIN MANUAL OR ELECTRONIC RECORDS IDENTIFYING, INDIVIDUALLY FOR EACH ORDER PROCESSED, FILLED, OR DISPENSED, THE NAME, INITIALS, OR IDENTIFICATION CODE OF EACH PHARMACIST RESPONSIBLE FOR THE FINAL VERIFICATION OF DISPENSING; THOSE RECORDS MUST INCLUDE DESCRIPTIONS OF ACTIONS TAKEN IN INTERPRETATION OF THE ORDER, ORDER ENTRY VERIFICATION, DRUG UTILIZATION REVIEW, DRUG COMPATIBILITY AND DRUG ALLERGY REVIEW, FINAL ORDER VERIFICATION, THERAPEUTIC INTERVENTION, AND REFILL AUTHORIZATION FUNCTIONS PERFORMED AT THAT PHARMACY OR BY THAT PHARMACIST;

(2) REPORT TO THE BOARD AS SOON AS PRACTICAL THE RESULTS OF ANY LICENSE DISCIPLINARY ACTION TAKEN BY A REGULATORY AGENCY IN ANOTHER LICENSING JURISDICTION INVOLVING A PHARMACY OR PHARMACIST PARTICIPATING IN SHARED PHARMACY SERVICES;

(3) MAINTAIN A MECHANISM FOR TRACKING THE ORDER DURING EACH STEP OF THE PROCESSING AND FILLING PROCEDURES PERFORMED AT THE PHARMACY OR BY THAT PHARMACIST;

(4) PROVIDE FOR ADEQUATE SECURITY TO PROTECT THE CONFIDENTIALITY AND INTEGRITY OF PATIENT INFORMATION;

(5) PROVIDE FOR INSPECTION OF ANY REQUIRED RECORD OR INFORMATION NO LATER THAN 72 HOURS AFTER ANY REQUEST BY THE BOARD OR ITS DESIGNEE. (E) EACH PHARMACY PARTICIPATING IN SHARED PHARMACY SERVICES, IF A (1) REQUESTING PHARMACY, SHALL HAVE A CURRENT IN-STATE PHARMACY LICENSE ISSUED UNDER AS 08.80.157 AND THIS CHAPTER; (2) FILLING PHARMACY, SHALL EITHER (A) HAVE A CURRENT IN-STATE PHARMACY LICENSE ISSUED UNDER AS 08.80.157 AND THIS CHAPTER; OR (B) BE REGISTERED AS AN OUT-OF-STATE PHARMACY UNDER AS 08.80.158 AND THIS CHAPTER. (F) EACH

PARTICIPANT IN SHARED PHARMACY SERVICES SHALL JOINTLY DEVELOP, IMPLEMENT, REVIEW, REVISE, AND COMPLY WITH JOINT POLICIES AND PROCEDURES FOR SHARED PHARMACY SERVICES. EACH PARTICIPANT IS REQUIRED TO MAINTAIN ONLY THOSE PORTIONS OF THE JOINT POLICIES AND PROCEDURES THAT RELATE TO THAT PARTICIPANT'S OPERATIONS. THE POLICIES AND PROCEDURES MUST (1) OUTLINE THE RESPONSIBILITIES OF EACH PARTICIPANT; (2) INCLUDE A LIST THAT CONTAINS (A) EACH PHARMACY PARTICIPATING IN SHARED PHARMACY SERVICES, AND EACH PHARMACIST ACTING INDEPENDENTLY OF A PHARMACY AND PARTICIPATING IN SHARED PHARMACY SERVICES; (B) THE NAME, ADDRESS, AND TELEPHONE NUMBER OF EACH OF THOSE PARTICIPANTS; AND (C) THE LICENSE NUMBERS FOR ALL LICENSES HELD BY EACH OF THOSE PARTICIPANTS; AND (3) ADDRESS (A) PATIENT NOTIFICATION THAT MEETS THE REQUIREMENTS OF THIS SECTION; (B) THE ADEQUATE PROTECTION OF THE CONFIDENTIALITY AND INTEGRITY OF PATIENT INFORMATION; (C) DISPENSING PRESCRIPTION ORDERS WHEN THE FILLED ORDER IS NOT RECEIVED OR THE PATIENT COMES IN BEFORE THE ORDER IS RECEIVED; (D) THE MAINTENANCE OF MANUAL OR ELECTRONIC RECORDS THAT MEET THE REQUIREMENTS OF THIS SECTION; (E) COMPLIANCE WITH FEDERAL AND STATE LAWS; AND (F) THE OPERATION OF A CONTINUOUS QUALITY IMPROVEMENT PROGRAM FOR SHARED PHARMACY SERVICES, DESIGNED TO OBJECTIVELY AND SYSTEMATICALLY MONITOR AND EVALUATE THE QUALITY AND APPROPRIATENESS OF PATIENT CARE, PURSUE OPPORTUNITIES TO IMPROVE PATIENT CARE, AND RESOLVE IDENTIFIED PROBLEMS. (G) NOTHING IN THIS SECTION PREVENTS AN INDIVIDUAL PHARMACIST LICENSED IN THIS STATE WHO IS EMPLOYED BY OR WORKING UNDER A CONTRACT WITH A PHARMACY, OR PREVENTS A LICENSED PHARMACY INTERN OR PHARMACY TECHNICIAN WORKING UNDER THE SUPERVISION OF THAT LICENSED PHARMACIST, FROM ACCESSING THE ELECTRONIC DATABASE OF THAT PHARMACY FROM INSIDE OR OUTSIDE THE

PHARMACY AND PROCESSING A PRESCRIPTION ORDER IN COMPLIANCE WITH AS 08.80 AND THIS CHAPTER IF (1) THE PHARMACY HAS ESTABLISHED CONTROLS TO PROTECT THE PRIVACY AND SECURITY OF CONFIDENTIAL RECORDS; AND (2) THE PHARMACIST, PHARMACY INTERN, OR PHARMACY TECHNICIAN DOES NOT DUPLICATE, DOWNLOAD, OR REMOVE DATA FROM THE PHARMACY'S ELECTRONIC DATABASE. (H) A PHARMACIST WORKING INDEPENDENTLY OUTSIDE OF THE STATE MAY PARTICIPATE IN SHARED PHARMACY SERVICES WITH AN INSTITUTIONAL PHARMACY IN THIS STATE IF THE PHARMACIST HOLDS (1) A CURRENT LICENSE AS A PHARMACIST ISSUED UNDER AS 08.80 AND THIS CHAPTER; AND (2) A CURRENT LICENSE TO PRACTICE AS A PHARMACIST ISSUED BY THE LICENSING JURISDICTION WHERE THE PHARMACIST IS WORKING. (I) THE PHARMACIST-IN-CHARGE OF THE REQUESTING PHARMACY MUST ENSURE COMPLIANCE WITH THE APPLICABLE REQUIREMENTS OF AS 08.80 AND THIS SECTION. AUTHORITY: AS 08.80.005 AS 08.80.157 AS 08.80.158 AS 08.80.030 -30- 12 AAC 52.446. SHARED PHARMACY SERVICES DURING EMERGENCY. (A) NOTWITHSTANDING 12 AAC 52.445, DURING A DISASTER EMERGENCY DECLARED BY THE GOVERNOR, A PHARMACY PARTICIPATING IN SHARED PHARMACY SERVICES, OR A PHARMACIST ACTING INDEPENDENTLY OF A PHARMACY AND PARTICIPATING IN SHARED PHARMACY SERVICES, SHALL DO SO IN ACCORDANCE WITH THIS SECTION. (B) DURING A DISASTER EMERGENCY DECLARED BY THE GOVERNOR, A PHARMACIST, PHARMACIST INTERN, OR PHARMACY LICENSED OR REGISTERED UNDER AS 08.80 MAY PARTICIPATE IN SHARED PHARMACY SERVICES WITHOUT APPLYING FOR APPROVAL UNDER 12 AAC 52.443 AND 12 AAC 52.444. (C) EXCEPT AS PROVIDED IN (D) OF THIS SECTION, IF A FILLING PHARMACY OR FILLING PHARMACIST OR PHARMACIST INTERN DELIVERS A PRESCRIPTION MEDICATION DIRECTLY TO THE PATIENT OR THE PATIENT’S AGENT, THE FILLING PHARMACY OR FILLING PHARMACIST OR PHARMACIST INTERN SHALL PROVIDE, ON THE PRESCRIPTION CONTAINER OR ON A SEPARATE SHEET DELIVERED WITH

THE PRESCRIPTION CONTAINER, THE LOCAL TELEPHONE NUMBER AND, IF APPLICABLE, THE TOLL-FREE TELEPHONE NUMBER OF THE FILLING PHARMACY OR FILLING PHARMACIST. (D) THE REQUIREMENT OF (C) OF THIS SECTION DOES NOT APPLY TO PRESCRIPTION MEDICATION DELIVERED TO PATIENTS IN FACILITIES WHERE A LICENSED HEALTH CARE PROFESSIONAL IS RESPONSIBLE FOR ADMINISTERING THE PRESCRIPTION MEDICATION TO THE PATIENT. (E) A PHARMACY PARTICIPATING IN SHARED PHARMACY SERVICES, OR A PHARMACIST ACTING INDEPENDENTLY OF A PHARMACY AND PARTICIPATING IN SHARED PHARMACY SERVICES, SHALL MAINTAIN MANUAL OR ELECTRONIC RECORDS IDENTIFYING, INDIVIDUALLY FOR EACH ORDER PROCESSED, FILLED OR DISPENSED, (1) THE NAME, INITIALS, OR IDENTIFICATION CODE OF EACH PHARMACIST OR PHARMACIST INTERN RESPONSIBLE FOR THE FINAL VERIFICATION OF DISPENSING; AND (2) THE PATIENT, DATE, DRUG, STRENGTH, DIRECTIONS, AND QUANTITY DISPENSED. (F) A PHARMACY PARTICIPATING IN SHARED PHARMACY SERVICES THAT DISTRIBUTES PRESCRIPTION DRUG ORDERS UNDER 12 AAC 52.235 USING A PHARMACY TECHNICIAN WHO HOLDS A NATIONAL CERTIFICATION SHALL MAINTAIN MANUAL OR ELECTRONIC RECORDS IDENTIFYING, INDIVIDUALLY FOR EACH ORDER PROCESSED, FILLED, OR DISTRIBUTED (1) THE NAME, INITIALS, OR IDENTIFICATION CODE OF EACH PHARMACY TECHNICIAN WHO HOLDS A NATIONAL CERTIFICATION; AND (2) THE PATIENT, DATE, DRUG, STRENGTH, DIRECTIONS, AND QUANTITY DISTRIBUTED. (G) NOTHING IN THIS SECTION PREVENTS A PHARMACIST WHO IS EMPLOYED BY OR WORKING UNDER A CONTRACT WITH THE PHARMACY, OR PREVENTS A LICENSED PHARMACIST INTERN OR PHARMACY TECHNICIAN FROM ACCESSING THE ELECTRONIC DATABASE OF THAT PHARMACY FROM INSIDE OR OUTSIDE THE PHARMACY AND PROCESSING A PRESCRIPTION DRUG ORDER.
AUTHORITY: AS 08.80.005 AS 08.80.030]

12 AAC 52.200. Pharmacist-in-Charge

…

(c) A pharmacist designated to replace the pharmacist-in-charge of a pharmacy shall notify the board **in writing** within [10] **30** days of that designation. [, BY SUBMITTING A COMPLETED CHANGE OF PHARMACIST-IN-CHARGE FORM PROVIDED BY THE DEPARTMENT AND PAYING THE APPLICABLE FEES ESTABLISHED IN 12 AAC 02.105(3).]

Note to board: Regulations **NOT** included here but mentioned in the FY22 Annual Report:

- Inventory loss/notifications by wholesale drug distributors
- HB 145 regulations that must be implemented by July 2023 (I've included a summary in the annual report of areas the board needs to write regulations for)

Regulation Recommendations - Proposed Regulations for FY 2023

☐ **No Recommendations**
The Board has no recommendations for proposed regulations at this time.

☑ **Recommendations**
The Board has the following recommendations for proposed regulations:

The Board of Pharmacy recommends AMENDMENTS to:

- 12 AAC 52.130 - (Registration of Pharmacies Located Outside of the State) to update the language from "registration" to "license"
- 12 AAC 52.865 - (Reporting and Reviewing PDMP Information) to incorporate language on ASAP (American Society for Automation in Pharmacy) reporting fields for veterinary prescriptions.
- 12 AAC 52.920 - (Disciplinary Guidelines) to clarify applicability to (C) and (D) is only to the extent the individual is licensed under this chapter (AS 08).

The Board of Pharmacy recommends NEW SECTIONS for:

- Automated dispensing machines
- Pharmacy kiosks (lockers)
- Inventory losses by wholesale drug distributors
- Manufacturer applications
- Internet pharmacies
- Inventory losses by wholesale drug distributors

The Board of Pharmacy acknowledges it must CREATE/UPDATE regulations by July 1, 2023 corresponding with HB 145:

- 12 AAC 52.992 - Re-title and replace term, "independent administration of" with "prescribe" wherever applicable and incorporate pharmacy technician requirements/standards
- 12 AAC 52.994 - Re-title and replace term, "independent administration of" with "prescribe" wherever applicable
- 12 AAC 52.240 - Update collaborative practice section to incorporate language for general health and wellness, disease prevention, and self-limiting conditions
- 12 AAC 52.460 - Remove "dosage form" ate collaborative practice section to incorporate language for general health and wellness, disease prevention, and self-limiting conditions
- 12 AAC 52.NEW - establish standards for monitoring of drug therapy

From: Campbell, Christopher
To: Campbell, Christopher
Cc: Campbell, Christopher
Subject: FDA Authorizes Pharmacists to Prescribe Paxlovid with Certain Limitations
Date: Wednesday, July 6, 2022 9:15:43 AM
Attachments: image001.png

Hello-

The U.S. Food and Drug Administration's (FDA or Agency) Intergovernmental Affairs (IGA) team would like to share an important update with you. Today, FDA revised the Emergency Use Authorization (EUA) for Paxlovid (nirmatrelvir and ritonavir), to authorize state-licensed pharmacists to prescribe Paxlovid to eligible patients, with certain limitations to ensure appropriate patient assessment and prescribing of Paxlovid. Read more below.

Coronavirus (COVID-19) Update: FDA Authorizes Pharmacists to Prescribe Paxlovid with Certain Limitations

New Prescribing Authority Could Improve Access for Some Patients at High Risk for Severe COVID-19

"The FDA recognizes the important role pharmacists have played and continue to play in combatting this pandemic," said Patrizia Cavazzoni, M.D., director for the FDA's Center for Drug Evaluation and Research. "Since Paxlovid must be taken within five days after symptoms begin, authorizing state-licensed pharmacists to prescribe Paxlovid could expand access to timely treatment for some patients who are eligible to receive this drug for the treatment of COVID-19."
When testing positive for COVID-19, patients should first consider seeking care from their regular health care provider or locating a Test-to-Treat site in their area. While this action allows state-licensed pharmacists to prescribe Paxlovid with certain limitations as described below, community pharmacies not already participating as a Test-to-Treat site can decide if or how they will offer this service to patients.

Patients who have tested positive for COVID-19 and are seeking to determine their eligibility for receiving Paxlovid at locations where prescribing by state-licensed pharmacists is available should bring the following information to ensure that the state-licensed pharmacist has sufficient information to determine their eligibility to receive Paxlovid:

- Electronic or printed health records less than 12 months old, including the most recent reports of laboratory blood work for the state-licensed pharmacist to review for kidney or liver problems. State-licensed pharmacists could also receive this information through a consult with the patient's health care provider.
- A list of all medications they are taking, including over-the-counter medications so the state-licensed pharmacist can screen for drugs with potentially serious interactions with Paxlovid.

Under the limitations outlined in the authorization, the state-licensed pharmacist should

refer patients for clinical evaluation with a physician, advanced practice registered nurse, or physician assistant licensed or authorized under state law to prescribe drugs, if any of the following apply:

- Sufficient information is not available to assess renal and hepatic function.
- Sufficient information is not available to assess for a potential drug interaction.
- Modification of other medications is needed due to a potential drug interaction.
- Paxlovid is not an appropriate therapeutic option based on the current Fact Sheet for Healthcare Providers or due to potential drug interactions for which recommended monitoring would not be feasible.

Paxlovid is authorized for the treatment of mild-to-moderate COVID-19 in adults and pediatric patients (12 years of age and older weighing at least 40 kilograms or about 88 pounds) with positive results of direct SARS-CoV-2 viral testing, who are at high risk for progression to severe COVID-19, including hospitalization or death. Patients in the authorized population who report a positive home test result from a rapid antigen diagnostic test, or a positive PCR test, to their provider are eligible for Paxlovid under the EUA. Confirmation of a positive home rapid antigen diagnostic test with additional direct SARS-CoV-2 viral testing, such as a PCR, is not required. Antibody tests are not considered to be direct SARS-CoV-2 viral tests.

Additional Resources:

- Paxlovid EUA Letter of Authorization
- Frequently Asked Questions on the Emergency Use Authorization for Paxlovid
- FDA Updates on Paxlovid for Health Care Providers
- Emergency Use Authorization: Drugs and Non-Vaccine Biological Products
- Coronavirus Disease (COVID-19)
- Coronavirus Treatment Acceleration Program (CTAP)
- Test to Treat Locator
- COVID-19 Therapeutics Locator

FDA's Intergovernmental Affairs team is here to assist state/local/territorial/tribal officials, including the national associations representing them, on FDA policy-related matters. If you have questions related to this or other drug-related issues, please let me know if I can assist you further. My contact information is below.

For general FDA-related inquiries, please contact FDA's IGA staff at IGA@fda.hhs.gov

Christopher C. Campbell, M.A. (he/him/his)
Senior Intergovernmental Affairs Specialist
Office of the Commissioner/OPLIA
U.S. Food and Drug Administration
Phone: (202) 680-4058
Christopher.Campbell@fda.hhs.gov

FDA U.S. FOOD & DRUG ADMINISTRATION

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STATE OF ALASKA

Department of Commerce, Community, and Economic Development
Professional Licensing

ALASKA BOARD OF PHARMACY

September 22 - 23, 2022 Meeting

Board Packet

Alaska Board of Pharmacy Roster

Board Member Name	Initial Appointment	Reappointed	Term End
Justin Ruffridge, PharmD	03/01/2020	03/01/2019	03/01/2024
Ashley Schaber, PharmD	07/01/2021		03/01/2024
James Henderson, RPh	03/01/2017	03/01/2017	03/01/2025
Leif Holm, PharmD	03/01/2015		03/01/2023
Ramsey Bell, RPh	03/01/2022		03/01/2026
Vacant (Public Member)			
Vacant (Public Member)			

Position	Name
Chair	Justin Ruffridge
Vice Chair	Ashley Schaber
CSAC Chair/Delegate	Justin Ruffridge
Secretary	James Henderson

Updated 03/24/2022

ALASKA BOARD OF PHARMACY MEETING

TENTATIVE AGENDA

SEPTEMBER 22, 2022 – DAY 1

Dial: 871 6050 7807
Passcode: 074861

Discussion of the following topics may require executive session. Only authorized members will be permitted to remain in the Zoom room during executive session.

Board Members:

Justin Ruffridge, *PharmD (Chair)*

Ashley Schaber, *PharmD (Vice Chair)*

James Henderson, *RPh (Secretary)*

Ramsey Bell, *RPh*

Vacant, *Public Member*

Vacant, *Public Member*

Staff:

Laura Carrillo *Executive Administrator*

Bradley Johnson *Occupational Licensing Examiner*

Vacant, *Occupational Licensing Examiner*

Upcoming Meetings:

Nov. 17-18, 2022
Anchorage

Meeting Details

Meeting Name: September 22, 2022 - Alaska Board of Pharmacy Meeting

Meeting Start Time: 9:00 AM AKDT

Meeting Start Date: 09/22/2022 (Thursday)

Meeting End Time: 4:30 PM AKDT

Meeting End Date: 09/22/2022 (Thursday)

Meeting Location: Zoom & Anchorage (TBD)

Meeting Registration Link:

https://us02web.zoom.us/meeting/register/tZMscemtrjwiGtP4XtYOfDDhb7SvvHQcL5xa

Agenda

I. Agenda Item #1 – 9:00 a.m. Roll Call/Call to Order (Chair Ruffridge)
II. Agenda Item #2 – 9:02 a.m. Review/Approve Agenda (Chair Ruffridge)
III. Agenda Item #3 – 9:05 a.m. Ethics Disclosures (Chair Ruffridge)
IV. Agenda Item #4 – 9:06 a.m. Review/Approve Meeting Minutes (Chair Ruffridge)
    a. June 16, 2022 draft
V. Agenda Item #5 – 9:30 a.m. Investigative Update
VI. Agenda Item #6 – 10:30 a.m. Public Comment #1
VII. Agenda Item #7 – 10:40 a.m. Board Business

a. Application Review
b. Review Lost/Stolen Rx
c. Correspondence
d. Other

VIII. Agenda Item #8 – 12:00 p.m. Lunch

IX. Agenda Item #9 – 1:00 p.m. Division Update/Budget Report (Melissa Dumas)

X. Agenda Item #10 – 1:30 p.m. Subcommittee Updates

a. Controlled Substances Advisory Subcommittee
b. Board Chairs
c. Pharmacy Well-being
d. 42 CFR Part 2
e. Compounding (tabled during February 2022 meeting)

XI. Agenda Item #12 – 2:00 p.m. Industry Update

a. AKPhA
b. DHSS

XII. Agenda Item #13 – 2:15 p.m. PDMP Update

XIII. Agenda Item #14 – 2:30 p.m. Regulations #1

a. Regulations Process
b. Regulations Update (large project adopted June 16, 2022)
c. FY 2023 Regulations from EA draft/annual report
d. New Regulations
    i. License expiration by request for techs/interns
    ii. Uniformed service (coast guard and public health)
    iii. Pharmacy remodeling
    iv. Other

XIV. Agenda Item #15 – 4:15 p.m. Public Comment #2

XV. Agenda Item #16 – 4:30 p.m. Recess until Friday, September 23, 2022

Links

Board of Pharmacy Homepage: pharmacy.alaska.gov

Prescription Drug Monitoring Program State page: pdmp.alaska.gov

September 22, 2022 - Alaska Board of Pharmacy Meeting - Day 2

Alaska Division of Corporations, Business and Professional Licensing
https://us02web.zoom.us/meeting/register/tZckdO-oqTgsG9OKqbjnmAn0HWtv8gClqFja
Sep 23, 2022 9:00 AM - Sep 23, 2022 4:45 PM AKDT

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4. Agenda Item #4 - 9:10 a.m. Public Comment #3

5. Agenda Item #5 - 9:25 a.m. Regulations #2.....17

6. Agenda Item #6 - 11:30 a.m. Lunch

7. Agenda Item #7 - 12:30 p.m. Regulations #3

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9. Agenda Item #9 – 3:45 p.m. EA Recruitment

10. Agenda Item #10 - 4:15 p.m. Administrative Update

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- **B. Travel/conferences/training**
- **C. Schedule next meeting dates.....33**

11. Agenda Item #11 - 4:30 p.m. Public Comment #4

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DEPARTMENT OF COMMERCE, COMMUNITY, AND ECONOMIC DEVELOPMENT
DIVISION OF CORPORATIONS, BUSINESS AND PROFESSIONAL LICENSING

BOARD OF PHARMACY

CONDENSED MINUTES OF THE MEETING HELD *(JUNE 16, 2022)*

THESE ARE DRAFT MINUTES OF THE MEETING AND HAVE NOT BEEN APPROVED BY THE BOARD.

Date:	June 16, 2022
Time:	Scheduled @ 9:00 a.m.; actual start @ 9:30 a.m.
Location:	Zoom & Anchorage – Robert Atwood Building, Suite 1550, 500 W. 7th Ave, Anchorage, AK 99501
Attending:	Board Members: Justin Ruffridge, Ashley Schaber, Ramsey Bell, Leif Holm, James Henderson. Staff: Laura Carrillo, Bradley Johnson, Charley Larson, Lisa Sherrell, Michael Bowles, Melissa Dumas
Absent:	

Topic: Roll Call		
Brief Discussion:	N/A	
Motion:	N/A	
Recorded Votes:	*Justin Ruffridge*	*James Henderson (not yet present)*
	Ashley Schaber	
	Ramsey Bell	
	Leif Holm	
Action Items:	N/A	
Topic: Approve Agenda		
Brief Discussion:	*The board reviewed the agenda for June 16, 2022.*	
Motion:	• *Ashley Schaber motions to approve the agenda as written, seconded by Ramsey Bell, and approved unanimously. It is:* *RESOLVED to approve the June 16, 2022 agenda as written.*	
Recorded Votes:	*Justin Ruffridge*	*James Henderson (not yet present)*
	Ashley Schaber	
	Ramsey Bell	
	Leif Holm	
Action Items:	*N/A*	

Topic: Ethics disclosures		
Brief Discussion:	*Ashley Schaber: member of the AKPhA and legislative committee.* *Justin Ruffridge: candidate for state house*	
Motion:	*N/A*	
Recorded Votes:	*N/A*	
Action Items:	*N/A*	
Topic: Draft minutes		
Brief Discussion:	*The board reviewed the draft minutes from February 17-18, 2022 and the motion list from March 25, 2022.*	
Motion:	*Ashley Schaber motions to approve the minutes as written, seconded by Ramsey Bell, and approved unanimously. It is:* *RESOLVED to approve the February 17-18, 2022 draft minutes.*	
Recorded Votes:	*Justin Ruffridge*	*James Henderson (not yet present)*
	Ashley Schaber	
	Ramsey Bell	
	Leif Holm	
Action Items:	*Ms. Carrillo will send the February 2022 meeting minutes to Dr. Ruffridge and will request the final minutes be posted on the board's website.*	
Topic: PDMP Update		
Brief Discussion:	*Lisa Sherrell provides an update on: project assistant recruitment, communication module, data sharing with 17 states and Military Health System and configuring settings to include other jurisdictions in searches, delegate audit, awareness and feedback questionnaire highlights, statewide integration, consultant/analysis of PDMP, data overview (registration and reporting), reporting compliance monitoring.*	
Motion:	*N/A*	
Recorded Votes:	*N/A*	
Action Items:	*N/A*	
Topic: INV Update		
Brief Discussion:	The board reviewed the report from February 8, 2022 through June 2, 2022. Investigator Bowles opened 36 cases and closed 12.	

Motion:	*On a motion duly made by Ashley Schaber in accordance with AS 44.62.310(c)(2) and seconded by James Henderson, the board unanimously moves to enter executive session for the purpose of discussing subjects that tend to prejudice the reputation and character of any person, provided the person may request a public discussion. No request was made for public discussion. It is:* *RESOLVED to enter into executive session in accordance with AS 44.62.310(c)(2). Staff, Michael Bowles, Laura Carrillo, Bradley Johnson, Lisa Sherrell, and Carmen Pora are authorized to remain in the room.* *Off record for executive session at 10:08 a.m.* *On record from executive session at 10:32 a.m.*	
Recorded Votes:	*Justin Ruffridge*	*James Henderson*
	Ashley Schaber	
	Ramsey Bell	
	Leif Holm	
Motion:	• *Ramsey Bell motions to accept the imposition of civil fine for 2021-001208 in the amount of $300, seconded by James Henderson, and approved with one abstention by Ashley Schaber, it is:* *RESOLVED to accept the imposition of civil fine for 2021-001208.* • *Ramsey Bell motions to accept the imposition of civil fine for 2021-000940 in the amount of $250, seconded by James Henderson, and approved with one abstention by Ashley Schaber, it is:* *RESOLVED to accept the imposition of civil fine for 2021-000940.* • *Ramsey Bell motions to accept the imposition of civil fine for 2021-001079 in the amount of $250, seconded by James Henderson, and approved with one abstention by Leif Holm, it is:* *RESOLVED to accept the imposition of civil fine for 2021-001079.* • *Ramsey Bell motions to accept the imposition of civil fine for 2021-001195 in the amount of $300, seconded by James Henderson, and approved unanimously, it is:* *RESOLVED to accept the imposition of civil fine for 2021-001195.* • *Ramsey Bell motions to accept the imposition of civil fine for 2021-000733 in the amount of $500, seconded by James Henderson, and approved with one abstention by Leif Holm, it is:* *RESOLVED to accept the imposition of civil fine for 2021-000733.*	

	• *Ramsey Bell motions to accept the imposition of civil fine for 2021-000187 in the amount of $300, seconded by James Henderson, and approved with one abstention by Ashley Schaber, it is:* *RESOLVED to accept the imposition of civil fine for 2021-2021-000187.*	
Recorded Votes:	*Justin Ruffridge*	*James Henderson*
	Ashley Schaber	
	Ramsey Bell	
	Leif Holm	
Action Items:	*Dr. Ruffridge will send the signed imposition of civil fines to Investigator Bowles.*	
Topic: Public Comment		
Brief Discussion:	*Callista Carlton: requests language addressing kiosk placement (at least 10 feet from pharmacy)* *Brandy Seignemartin (AKPHA): thanks the board for their collaboration on HB 145.*	
Motion:	*N/A*	
Recorded Votes:	*N/A*	
Action Items:	*N/A*	
Topic: Statutes		
Brief Discussion:	*Dr. Ruffridge states that HB 306 to extend the board of pharmacy passed the legislature. Dr. Ruffridge states HB 145 also passed to expand pharmacist's authority; updates "independent administration" with "prescribe", addresses cooperative practice agreements, and insurance reimbursement. Ms. Carrillo states that regulations to implement HB 145 are due in July 2023. Dr. Ruffridge states SB 132 to exempt the Board of Veterinary Examiners from participation with the PDMP did not pass. Dr. Schaber states SB 210 related to pharmacy benefits managers and cost-savings to patients was a bill of interest but board did not take official position. The bill did not make to a committee hearing. Dr. Schaber states it relates to white and brown bagging, which were discussed by the board previously (patient choice).* *Dr. Ruffridge states the board should prepare a list of statutes to put forward for next session. Ms. Carrillo referred to preliminary list in the board's draft FY2022 annual report. Dr. Schaber agrees a subcommittee would be helpful.* *Off record at 10:55 a.m. for break.* *On record at 11:02 a.m. from break.*	
Motion:	*N/A*	
Recorded Votes:	*N/A*	

Action Items:	*N/A*
Topic: Pharmacy Locker Demo (Kiosks; Bryan Rigney)	
Brief Discussion:	*Mr. Rigney provides a demo on use of a pharmacy locker (kiosk); product is called iLocalBox. Mr. Rigney states it is an alternative to mail order pharmacy services, is secure, contactless, and a convenient way to increase patient access to medications and improve inherence; extends the reach of community pharmacies.* • *Safety and security: temperature-controlled system, complete chain of custody tracking, surveillance and alarm systems, package sensor technology, encryption, locking mechanisms.* • *Accuracy: single stock, prescriptions still checked by pharmacist, adjudication. Patient experience: contactless pick-up, no lines/waiting, order refills, telepharmacy consulting platform, self-informed notifications and reminders, ease of payment* • *Traceability and reporting: provides complete auditability and medication retraction prior to pick-up (assignment, stocking, pick-up, expiration, etc.)* *Ramsey Bell asks to provide example of where this would be located; asks who would provide the consultation/answering services if it is a 24/hour service, e.g.: would it be pharmacist in Alaska? Mr. Rigney states it is up to the client.* *Ashley Schaber asks temperature control. Mr. Rigney states iLocalBox provides options* *for clients to set temperature thresholds; i temperatures cross thresholds, medication can be put on hold so patient cannot pick up. Ms. Carrillo asks about error rate and how often temperatures have crossed thresholds. Ms. Carrillo also asks about how a pharmacy may have their locker serviced. Mr. Rigney states there has been no instance of temperature failure since implementation; iLocalBox provides maintenance for servicing.* *Justin Ruffridge comments on licensure requirement for individuals servicing the state. Mr. Rigney responds that the company will defer to client.* *for clients to set temperature thresholds; i temperatures cross thresholds, medication can be put on hold so patient cannot pick up. Ms. Carrillo asks about error rate and how often temperatures have crossed thresholds. Ms. Carrillo also asks about how a pharmacy may have their locker serviced. Mr. Rigney states there has been no instance of temperature failure since implementation; iLocalBox provides maintenance for servicing.* *Justin Ruffridge comments on licensure requirement for individuals servicing the state. Mr. Rigney responds that the company will defer to client.* *Callista Carlton states that long-term locker pick-up is a sustainable long-term solution for access to care post-COVID.*

	Leif Holm inquiries about placement of kiosks in relation to the location of the pharmacy. *Justin Ruffridge asks about the difference between a kiosk (locker) and an automated dispensing cabinet. Mr. Rigney states the kiosks are distinct from automated cabinets as it does not perform pill counts. Dr. Ruffridge asks about states which differentiate between lockers and cabinets. Mr. Rigney references Oregon. Ms. Carrillo states kiosks rules can be implemented in regulation; the board may specify placement requirements. Ms. Carrillo states licensing of automated dispensing cabinets requires legislation.*
Motion:	*N/A*
Recorded Votes:	*N/A*
Action Items:	*N/A*
Topic: Board Business (annual report, 2023 strategic plan, application review, subcommittees, position statements, crisis stabilization units)	
Brief Discussion:	*Ms. Carrillo provides an overview of the draft annual report, including highlights in the previous year and projects to follow in FY2023. Ms. Carrillo summarizes legislative and regulatory removals, amendments, and additions, including a high-level summary of changes needed to implement HB 145 by next summer. Justin Ruffridge and Ramsey Bell notes corrections needed on the annual report regarding board membership details.* *Ms. Carrillo provides an overview of the board's strategic plan, which adds strategies around the DSCSA and system integrations to improve licensing and administrative functions. The board reviews emergency and regular applications, collaborative practice agreements, and DEA 106 forms.* *Ms. Sherrell explains the need for the board to address 42 CFR Part 2 related to medication assisted treatment; suggests a subcommittee to bring opioid treatment providers and office-based providers together to the table for input. Ms. Sherrell adds she has been meeting with a number of providers around this topic and the collection of its data in the PDMP. Ms. Sherrell states it is a complex matter and should involve stakeholders, including a representative from the Board of Pharmacy. Ms. Carrillo reiterates that Department of Law has opined the board is required to issue regulations. Ms. Carrillo states the subcommittee can help facilitate development of regulations.* *The board reviewed correspondence from Dr. Andre Neptune regarding crisis stabilization unit. Ms. Carrillo recalls a legal opinion previously provided on alternative care sites. Dr. Ruffridge agrees this may be related, but requests follow-up to clarify types of services being provided.*
Motion:	• *Ashley Schaber motions to approve the board's FY2022 annual report as amended and the 2023 strategic plan as written, seconded by Ramsey Bell, and approved unanimously, it is:* *RESOLVED to approve the FY2022 Annual Report as amended and 2023 Strategic Plan as written.*

	• *On a motion duly made by Ashley Schaber in accordance with AS 44.62.310(c)(2) and seconded by James Henderson, the board unanimously moves to enter executive session for the purpose of discussing subjects that tend to prejudice the reputation and character of any person, provided the person may request a public discussion.* *RESOLVED to enter into executive session in accordance with AS 44.62.310(c)(2). Staff, Laura Carrillo and Bradley Johnson are authorized to remain in the room.* *Off record at 12:13 p.m.* *On record at 1:06 p.m.* • *Ashley Schaber motions to approve the technician license application, 187538, for Marlene Rivas, seconded by Ramsey Bell, and approved unanimously with one absence with James Henderson, it is:* *RESOLVED to approve the application for Marlene Rivas.* • *Ashley Schaber motions to approve the collaborative practice agreement for Providence Kodiak Island Medical Center - #144054, seconded by Ramsey Bell, and approved unanimously, it is:* *RESOLVED to approve the collaborative practice agreement for Providence Kodiak Island Medical Center.* • *Ashley Schaber motions to table the wholesale drug distributor application for BWXT Medical Ltd. pending additional information on jurisdiction, seconded by Ramsey Bell, and tabled unanimously, it is:* *RESOLVED to table the wholesale drug distributor application for BWXT Medical Ltd.* • *Ashley Schaber motions to table the two shared services applications for Pipeline Rx pending additional guidance from the division, seconded by Ramsey Bell, and tabled unanimously, it is:* *RESOLVED to table the shared pharmacy services applications for Pipeline Rx.*	
	• *Ashley Schaber motions to create a subcommittee to implement 42 CFR Part 2, seconded by James Henderson, and approved unanimously, it is:* *RESOLVED to create a subcommittee for 42 CFR Part 2.*	
Recorded Votes:	*Justin Ruffridge*	*James Henderson*
	Ashley Schaber	

	Ramsey Bell	
	Leif Holm	
Action Items:	*Ms. Carrillo will distinguish between kiosks and automated dispensing cabinets in the annual report and will post the annual report to the board's website.*	
	Ms. Carrillo will see whether defining "jurisdiction" is in statute or regulation. Language in law book seems to imply to applicants outside of Alaska but within the U.S.	
	Ms. Carrillo will post the FY 2023 Strategic Plan to the board's website.	
	Ms. Carrillo will notify emergency permit applicants that they do not qualify; instruct them to apply for permanent license.	
	Ms. Carrillo will process the collaborative practice agreement for Providence Kodiak Island Medical Center.	
	Ms. Carrillo will request a legal opinion regarding jurisdiction of foreign applicants.	
	Ms. Carrillo will follow-up with Costco pharmacy #10, PHAR339, on employee CS theft.	
	Ms. Schaber and Ms. Sherrell will convene as part of the 42 CFR Part 2 Subcommittee.	
	Ms. Carrillo will follow-up with Dr. Neptune on crisis stabilization units to clarify what specific pharmacy services will be provided.	
	Ms. Carrillo will add technician and intern licenses/ability to expire license upon request with approval by the EA as a new regulation project for the September 2022 meeting; possible amendment to language requiring technician license to be returned.	
Topic: Budget Report		
Brief Discussion:	*Ms. Dumas reviewed the board's fee analysis incorporating regulation of pharmaceutical manufacturers. The proposed fee is $550, consistent with the initial and renewal fees for other facilities, including non-resident wholesale drug distributors, outsourcing facilities, and 3PLs. Ms. Dumas shares the division may anticipate around 170 wholesaler applications; Ms. Carrillo states this number comes from the number of current wholesalers the board licenses and the national ratio of wholesalers to pharmaceutical manufacturers (8:1). Ms. Carrillo adds that the board currently regulates manufacturers as wholesalers, which is inconsistent with DSCSA rules.* *James Henderson motions to concur with division's proposal and receives unanimous support.*	
Motion:	*N/A*	
Recorded Votes:	*N/A*	
Action Items:	*Ms. Carrillo will coordinate with Ms. Dumas and regulations specialist, Jun Maiquis, on implementing manufacturer regulations concurrent with the new fees.*	
Topic: Subcommittee Updates		
Brief Discussion:	*CSAC – Ms. Lindemuth no longer with the board; to be chaired by Dr. Ruffridge.*	
	PDMP chairs – no longer meeting (tabled)	
	Pharmacy well-being subcommittee: Ashley Schaber recalls this has not officially been formed, but that she and Ms. Carrillo reached out to the Department of Labor on	

	collaboration. Ms. Carrillo shares that the Dept. of Labor would not participate but could provide data on employment trends. Ms. Carrillo shares there is a well-being index survey that is distributed by the NABP for Alaska's district.	
	Compounding subcommittee (tabled)	
Motion:	• *Ashley Schaber motions to create a subcommittee to implement a Pharmacy Well-Being Subcommittee, seconded by Ramsey Bell, and approved unanimously, it is:* *RESOLVED to create a subcommittee for pharmacy well-being.*	
Recorded Votes:	*Justin Ruffridge*	*James Henderson*
	Ashley Schaber	
	Ramsey Bell	
	Leif Holm	
Action Items:	*Ashley Schaber and Ramsey Bell will convene for the Pharmacy Well-Being Subcommittee.*	
Topic: Industry Updates		
Brief Discussion:	*Brandy Seignemartin (AKPhA): supporting federal efforts for PBM regulation (SB 293); asking Sen. Sullivan to sign off on the federal legislation because he is part of the commerce committee. PBM regulation is critically important; working on it at the state level also incorporates white and brown bagging (patient choice). Dr. Seignemartin expresses interest in participating in the well-being subcommittee. participate in well-being subcommittee.* *Dr. Seignemartin shares that the association's annual leadership summit is September 23-24, 2022 and shares there is an upcoming webinar on pediatric vaccination approval on July 23, 2022. Also shares there is a student pharmacist rotation opportunity and that the preliminary schedule for the Annual Meeting is February 17-19, 2023.* *Ms. Carrillo states the board's September meeting may conflict with the leadership summit and suggests the board could reschedule.*	
Motion:	*N/A*	
Recorded Votes:	*N/A*	
Action Items:	*N/A*	
Topic: Regulations		
Brief Discussion:	*Ms. Carrillo shares that regulations related to military permits, emergency permits, executive administrator duties, and renewal will take effect on July 7, 2022. Ms. Carrillo also shares that the public comment period for the board's large regulation project ended June 13, 2022; comments are included in the board's packet for review.* *The board expresses concern about the State Medical Board's corresponding regulations (12 AAC 40.983) to 12 AAC 52.240 dealing with cooperative/collaborative practice agreements. Several members of the board express a desire to peel off this regulation until the language in 12 AAC 40.983 and concerns around the physical exam*	

	requirement is resolved. Ms. Carrillo suggests a subcommittee to include a representative from the Medical Board. *The board discusses new regulations to release for public comment (FY 2023 regulations), including veterinary reporting to the PDMP.* *The board discusses regulations to pursue in FY2023, including regulations to implement HB 145.*	
Motion:	• *Ashley Schaber motions to adopt the large regulations project as presented at the June 16, 2022, with review of public comments received through June 13, 2022, except for the proposed amendments to 12 AAC 52.240. With the motion seconded by James Henderson, and approved unanimously, it is:* *RESOLVED to adopt the proposed changes to the following regulations as publicly noticed: 12 AAC 52…* *.020,.030, .040, .070, .080, .092, .095, .120, .130, .140, .200, .230, .470, .585, .620, 635, .696, .697, .860, .865, and .990.* • *James Henderson motions to remove 12 AAC 52.865(b)(2), seconded by Leif Holm, and approved with one abstention by Justin Ruffridge.* *RESOLVED to remove 12 AAC 52.865(b)(2) in the draft for FY2023 regulations.* • *Justin Ruffridge motions to establish a regulations subcommittee, seconded by James Henderson, and approved unanimously, it is.* *RESOLVED to establish a regulations subcommittee.*	
Recorded Votes:	*Justin Ruffridge*	*James Henderson*
	Ashley Schaber	
	Ramsey Bell	
	Leif Holm	
Action Items:	*Ms. Carrillo will add uniformed service (coast guard and public health service) regulations to the September 2022 meeting.*	
	The board will address 12 AAC 52.865(h) at the September 2022 meeting.	
	The regulations subcommittee will look at all FY 2023 regulations in advance of the September 2022 meeting.	
	Ms. Carrillo sign the adoption order for the large regulations project and send it to Mr. Maiquis.	
Topic: Administrative Update		

Brief Discussion:	*Ms. Carrillo provides overview of Governor's Administrative Order regarding license priorities, shares update on missing annual reports from out-of-state pharmacies, provides update on renewal forms and revisions, and reviews the board's task list since November 2021.* *No motions or action items.*

Next Meeting:	September 22 – 23, 2022
Adjournment:	4:32 p.m.

Investigative Process Overview

PRESENTED BY INVESTIGATIONS

Who Are We?

State of Alaska

↓

Department of Commerce, Community, and Economic Development

↓

Division of Corporations, Business and Professional Licensing

↓

Investigations

What Do We Do?

The mission of the Division of Corporations, Business and Professional Licensing is to ensure that **competent**, **professional** and **regulated** commercial services are available to Alaska consumers.

Three License Types

01

Professional License: Individual specialty such as a Nurse, Doctor, Dentist, Massage Therapist, etc…

02

Business License: (AS 43.70.020) If providing any service for the exchange of money, a business license is required in the state of Alaska.

03

Corporate Entity (Corporation): A group of persons who are deemed in law to be a single legal ***entity***. The ***corporate entity*** is legally distinct from its members; it has legal personality and can hold property, sue and be sued in its own name as if it were a natural person.

Who Needs a Professional License Through the State of Alaska?

- Acupuncturists
- Architects, Engineers, and Land Surveyors
- Athletic Trainers
- Audiologists & Speech-Language Pathologists
- Barbers & Hairdressers
- Behavior Analysts
- Big Game Commercial Services Board
- Chiropractic Examiners
- Collection Agencies
- Concert Promoters
- Construction Contractors
- Dental Examiners
- Dietitians & Nutritionists
- Dispensing Opticians
- Electrical Administrators
- Euthanize Domestic Animals
- Geologists
- Guardians & Conservators
- Hearing Aid Dealers
- Home Inspectors
- Marine Pilots
- Marital & Family Therapy
- Massage Therapists
- Mechanical Administrators
- Medical Board
- Midwives
- Morticians
- Naturopathy
- Nursing
- Nurse Aide Registry
- Nursing Home Administrators
- Optometry
- Pawnbrokers
- Pharmacy
- Physical Therapy & Occupational Therapy
- Prescription Drug Monitoring Program
- Professional Counselors
- Psychologist and Psychological Associate
- Public Accountancy
- Real Estate Appraisers
- Real Estate Commission
- Social Work Examiners
- Telemedicine Business Registry
- Underground Storage Tank Worker
- Veterinary Examiners

What Do We Investigate?

Statutes & Regulations

- **AS = Alaska Statutes:** Are passed by either the US Congress or State Legislatures: The legislatures create bills that, when passed by a vote, become statutory law.
- **AAC = Alaska Administrative Code // Regulation**: Regulations, on the other hand, are standards and rules adopted by administrative agencies (Boards) that govern how laws will be enforced.

Difference between Statutes and Regulations:
Although many people use the terms "statute" and "regulation" interchangeably, they aren't the same. Governing bodies, such as the United States Congress or a state legislature, enact statutes. On a local level, the statutes enacted by municipalities are known as ordinances. Regulations put those statutes to work, fleshing out the details.

Different Roles

EXAMPLE:

- AK Legislature creates Statutes.
- Boards create Regulations.
- Investigations investigate ***alleged violations*** of Statutes and/or Regulations.
- Board Members **verify whether or not a violation occurred** when reviewing a case from investigations.

Investigators gather information. Licensed board members determine if a violation of statute or regulation has occurred.

How Does Someone File a Complaint?

Public Website

https://www.commerce.alaska.gov/web/cbpl/Investigations.aspx

THE STATE of ALASKA
Department of Commerce, Community, and Economic Development
Division of Corporations, Business and Professional Licensing

ADM
FOR DIVISION USE ONLY

Investigations Section
550 West 7th Avenue, Suite 1500, Anchorage, AK 99501
Phone: (907) 269-8174 · Fax: (907) 269-8195
Website: *CBPLinvestigations.Alaska.Gov*
Email: *Investigations@Alaska.Gov*

Investigations — Request for Contact

The division investigates matters pertaining to business licenses, the sale of tobacco products, and licensed professionals. Not all issues will fall within our jurisdiction. You may have to contact other agencies for assistance. We encourage you to call to ensure that we are able to assist you.

This is only a request for contact. You may submit this form via US Mail, fax, or email, to the contact information listed above. Once the division has reviewed this information you will be contacted and may be asked to fill out a complaint package.

PART I Your Contact Information

Complete Name:	First Name:	Middle Name:	Last Name:		
Mailing Address:	Address:	City:	State:	Zip Code:	
Contact Phone:	( ) –				
Email Address:					

PART II Description of Incident

Type of Business or Profession Involved:	
Name(s) of Person or Business Involved:	
Date(s) Which Incident Occurred:	
Brief Description of Incident:	

08-4604 Rev 05/24/18 Investigations — Request for Contact

Contact Us Directly

Contact Us

State of Alaska/DCCED
Division of Corporations, Business and Professional Licensing
Investigations Section
550 West 7th Avenue, Suite 1500
Anchorage, AK 99501-3567
Phone: (907) 269-8174
Fax: (907) 269-8195

Email: Investigations@Alaska.gov

Next Step: Is the Complaint Jurisdictional?

- Review informal guidelines established by the Board or Commission, and the statutes and regulations of that specific practice area.
- If the complaint does not appear to allege a violation that is within the Board's jurisdiction, the Division may close the complaint.

Next Step: Is the Complaint Jurisdictional?

Complaints that are typically not jurisdictional are:

- Money matters
- "Bedside Manner"
- Anonymous complaints

The Complaint is Jurisdictional. What Happens Next?

The complainant is asked to complete a complaint packet.

The packet provides the complainant to:

- Provide a summary of the incident
- Include supporting documentation
- Sign a release of information
- Sign an Affidavit

Complaint Packet

STATE OF ALASKA
DEPARTMENT OF
COMMERCE
COMMUNITY AND
ECONOMIC DEVELOPMENT

Division of Corporations, Business and Professional Licensing – Investigations
550 West 7th Avenue, Suite 1500, Anchorage, AK 99501-3567
Telephone: (907) 269-8437 Fax: (907) 269-8195 Website: www.commerce.state.ak.us/oce

COMPLAINT FILED BY:

NAME (Last, First Middle Initial)

ADDRESS

CITY STATE ZIP

WORK PHONE HOME PHONE

COMPLAINT FILED AGAINST:

NAME and TITLE

ADDRESS

CITY STATE ZIP

WORK PHONE HOME PHONE

SUMMARY OF COMPLAINT

Please describe your complaint in detail. If necessary, please use an additional sheet of paper. Please provide any additional supporting documents.

AFFIDAVIT

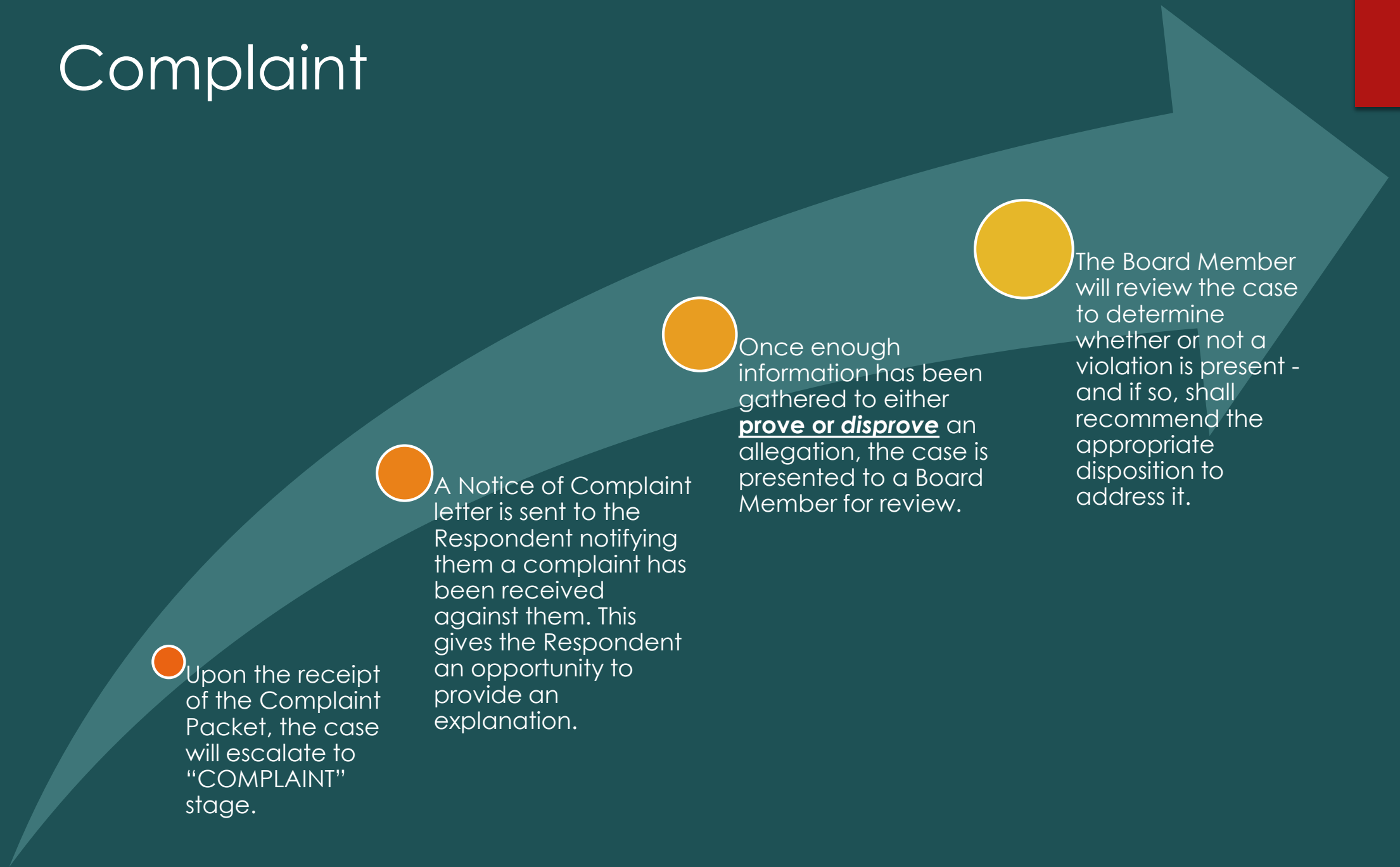
State of _____ City/Borough of _____

I, _____ hereby state under penalty of unsworn falsification: That I am the complainant in the named above and to the best of my knowledge and belief, this statement is true and correct.

Signature of Complainant: _____ Date: _____

AS 11.56.210(a)(2) of the Alaska Statutes makes it a class A misdemeanor of offense for a person to intentionally issue a false written or recorded statement, which is punishable by imprisonment for not more than one (1) year, a $5,000 fine, or both.

Complaint



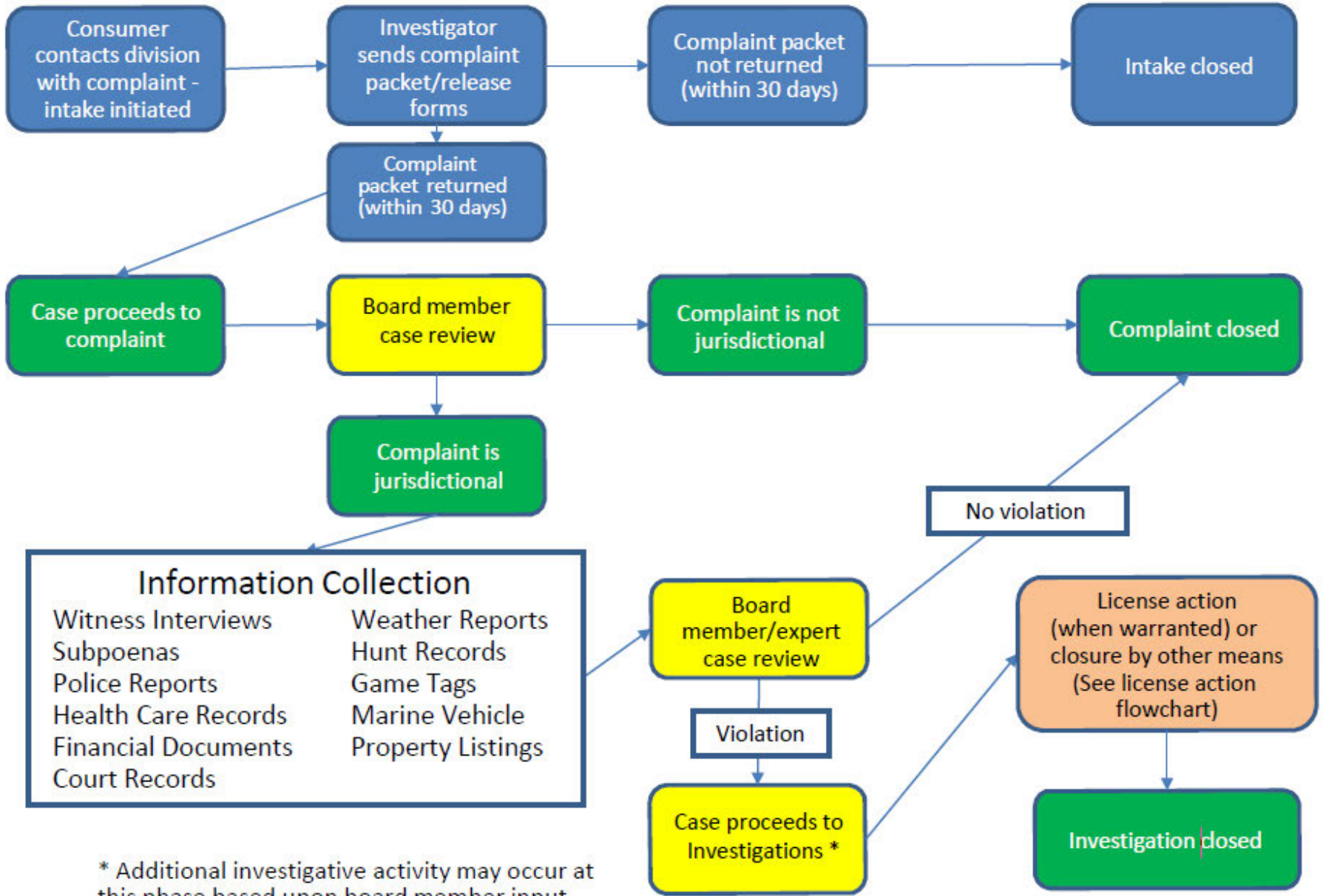
Upon the receipt of the Complaint Packet, the case will escalate to "COMPLAINT" stage.

A Notice of Complaint letter is sent to the Respondent notifying them a complaint has been received against them. This gives the Respondent an opportunity to provide an explanation.

Once enough information has been gathered to either **prove or *disprove*** an allegation, the case is presented to a Board Member for review.

The Board Member will review the case to determine whether or not a violation is present - and if so, shall recommend the appropriate disposition to address it.

Investigative Process



* Additional investigative activity may occur at this phase based upon board member input.

Three Stages of "Investigation"

INTAKE:
Preliminary information stage

- Typically generated upon receipt of a Request for Contact form or a Referral Email.

COMPLAINT:
Fact-gathering stage

- Escalates when a Complaint Packet is received.

INVESTIGATION:
Violation verified stage

- Following a Board Member review, case escalates when a Board Member confirms a violation is present.

Investigation

After a licensed Board Member Reviewer determines a violation of statute or regulation is present:

- Case escalates to "INVESTIGATION"
- A Notice of Investigation (NOI) is sent to the Respondent, notifying them a violation was verified.
- RBM recommends the appropriate action (Disciplinary or Non-Disciplinary) to address the violation:

Disciplinary Action:

- Consent Agreement
- Probation
- Civil Fine
- Continuing Education
- Etc..

Non-Disciplinary Action:

- Non-Disciplinary Letter of Advisement

Three Investigation Case Types

- **Application Matters:** Inquires initiated by Licensing to review applications for truthfulness & accuracy.
- **Consumer Complaints**: Inquiries initiated upon the receipt of a Complaint Packet (or written complaint).
- **Inspections:** Onsite inspections to ensure operations are in accordance to AS 43.70 & 12 AAC 12

Confidentiality

- Investigations are required by statute to be kept confidential.
- This often prevents the complainant, licensee, and the Board from obtaining progress reports or information that may disclose the current status of an open investigation.
- This also protects the reputation of licensees who may be accused of wrongdoing but the allegations against them are unproven.
- Cases often involve other agencies, businesses, and practices; disclosing information during an on-going case can compromise the investigation, create conflicts for reviewing Board members, or result in unnecessary hardship to the licensee.

Questions / Discussion

INVESTIGATIVE OVERVIEW

THE STATE of ALASKA

Department of Commerce, Community, and Economic Development

DIVISION OF CORPORATIONS, BUSINESS AND PROFESSIONAL LICENSING

550 West Seventh Avenue, Suite 1500
Anchorage, AK 99501-3567
Main: 907.269.8160
Fax: 907.269.8156

MEMORANDUM

DATE: September 08, 2022

TO: Board of Pharmacy

THRU: Greg Francois, Chief Investigator DS

FROM: Michael Bowles, Investigator DS MPB

RE: Investigative Report for the September 22, 2022 Meeting

The following information was compiled as an investigative report to the Board for the period of June 03, 2022 thru September 08, 2022; this report includes cases, complaints, and intake matters handled since the last report.

Matters opened by the Paralegals in Anchorage and Juneau, regarding continuing education audits and license action resulting from those matters are covered in this report.

OPEN - 30

Case Number	Violation Type	Case Status	Status Date
OUT OF STATE PHARMACY			
2022-000745	Violation of licensing regulation	Intake	08/05/2022
2022-000826	Violation of licensing regulation	Intake	08/31/2022
2022-000434	Violation of licensing regulation	Complaint	06/02/2022
2022-000476	Violation of licensing regulation	Complaint	06/14/2022
2022-000746	Violation of licensing regulation	Complaint	09/01/2022
2021-000111	Violation of licensing regulation	Monitor	03/22/2022
2022-000213	Falsified application	Investigation	08/15/2022
2022-000215	Violation of licensing regulation	Investigation	05/31/2022
PHARMACIST			

2021-001312	Fraud or misrepresentation	Complaint	02/03/2022
2022-000485	Drug diversion	Complaint	06/14/2022
2022-000783	Unlicensed practice or activity	Complaint	08/22/2022

PHARMACIST INTERN

2022-000435	Unlicensed practice or activity	Investigation	08/22/2022

PHARMACY

2022-000782	Violation of licensing regulation	Intake	08/22/2022
2022-000634	Violation of licensing regulation	Complaint	07/14/2022
2021-000037	PDMP Violation	Monitor	01/21/2021
2021-000775	Violation of licensing regulation	Investigation	08/27/2021
2021-000776	Violation of licensing regulation	Investigation	08/27/2021
2021-000784	Violation of licensing regulation	Investigation	08/27/2021
2022-000216	Violation of licensing regulation	Investigation	05/31/2022
2022-000424	Violation of licensing regulation	Investigation	09/06/2022

PHARMACY TECHNICIAN

2022-000815	Criminal action - conviction	Intake	08/29/2022
2022-000828	Criminal action - conviction	Intake	08/31/2022
2019-000721	Falsified application	Investigation	02/09/2021
2019-000936	Falsified application	Investigation	02/11/2021

WHOLESALE DRUG DEALER

2022-000827	Violation of licensing regulation	Intake	08/31/2022
2022-000829	Violation of licensing regulation	Intake	08/31/2022
2022-000749	Violation of licensing regulation	Complaint	08/10/2022
2022-000294	Violation of licensing regulation	Investigation	05/31/2022
2022-000354	Violation of licensing regulation	Investigation	06/30/2022
2022-000446	Violation of licensing regulation	Investigation	08/09/2022

Closed - 47

Case #	Violation Type	Case Status	Closed	Closure
OUT OF STATE PHARMACY				
2021-000468	Violation of licensing regulation	Closed-Investigation	06/03/2022	No Action - No Violation
2021-001208	Violation of licensing regulation	Closed-Investigation	08/15/2022	License Action
2022-000129	Falsified application	Closed-Investigation	06/16/2022	Advisement Letter
2022-000293	Violation of licensing regulation	Closed-Investigation	07/18/2022	No Action - No Violation
PHARMACIST				
2022-000503	Falsified application	Closed-Intake	06/16/2022	Review Complete
2022-000648	Unlicensed practice or activity	Closed-Intake	08/09/2022	Incomplete Complaint
2021-001241	Unprofessional conduct	Closed-Complaint	09/08/2022	No Action - No Violation
2022-000287	Negligence	Closed-Complaint	08/08/2022	No Action - No Violation
PHARMACY				
2022-000604	Compliance Inspection	Closed-Intake	06/29/2022	Compliance
2022-000605	Compliance Inspection	Closed-Intake	06/29/2022	Compliance
2022-000606	Compliance Inspection	Closed-Intake	06/29/2022	Compliance
2022-000607	Compliance Inspection	Closed-Intake	06/29/2022	Compliance
2022-000608	Compliance Inspection	Closed-Intake	06/29/2022	Compliance
2022-000609	Compliance Inspection	Closed-Intake	06/29/2022	Compliance
2022-000610	Compliance Inspection	Closed-Intake	06/29/2022	Compliance
2022-000611	Compliance Inspection	Closed-Intake	06/29/2022	Compliance
2022-000612	Compliance Inspection	Closed-Intake	06/29/2022	Closed - Case Opened
2022-000613	Compliance Inspection	Closed-Intake	06/29/2022	Compliance
2022-000682	Advertising	Closed-Intake	08/22/2022	Incomplete Complaint
2021-001187	Violation of licensing regulation	Closed-Complaint	09/07/2022	No Action - No Violation
2022-000614	Violation of licensing regulation	Closed-Complaint	08/15/2022	No Action - No Violation
2021-000288	Falsified application	Closed-Investigation	07/14/2022	No Action - No Violation
2022-000187	Violation of licensing regulation	Closed-Investigation	08/15/2022	License Action
2022-000547	Compliance Inspection	Closed-Division Inspection	06/16/2022	Compliance

2022-000548	Compliance Inspection	Closed-Division Inspection	06/16/2022	Compliance
2022-000549	Compliance Inspection	Closed-Division Inspection	06/16/2022	Compliance
2022-000550	Compliance Inspection	Closed-Division Inspection	06/16/2022	Compliance
2022-000551	Compliance Inspection	Closed-Division Inspection	06/16/2022	Compliance
2022-000552	Compliance Inspection	Closed-Division Inspection	06/16/2022	Compliance
2022-000553	Compliance Inspection	Closed-Division Inspection	06/16/2022	Compliance
2022-000554	Compliance Inspection	Closed-Division Inspection	06/16/2022	Compliance
2022-000555	Compliance Inspection	Closed-Division Inspection	06/16/2022	Compliance
2022-000556	Compliance Inspection	Closed-Division Inspection	06/16/2022	Compliance
2022-000557	Compliance Inspection	Closed-Division Inspection	06/16/2022	Compliance
2022-000558	Compliance Inspection	Closed-Division Inspection	06/16/2022	Compliance
2022-000632	Compliance Inspection	Closed-Division Inspection	07/11/2022	Compliance
2022-000633	Compliance Inspection	Closed-Division Inspection	07/11/2022	Closed - Case Opened
2022-000834	Compliance Inspection	Closed-Division Inspection	09/07/2022	Closed - Case Opened
2022-000835	Compliance Inspection	Closed-Division Inspection	09/07/2022	Closed - Case Opened
2022-000836	Compliance Inspection	Closed-Division Inspection	09/07/2022	Closed - Case Opened

PHARMACY TECHNICIAN

2022-000320	Contested license denial	Closed-Intake	06/17/2022	Other (See Abstract)

WHOLESALE DRUG DEALER

2022-000491	Violation of licensing regulation	Closed-Complaint	09/08/2022	No Action - No Violation
2021-000733	Falsified application	Closed-Investigation	08/15/2022	License Action
2021-000940	Violation of licensing regulation	Closed-Investigation	06/29/2022	License Action
2021-001079	Violation of licensing regulation	Closed-Investigation	06/29/2022	License Action
2021-001195	Violation of licensing regulation	Closed-Investigation	08/15/2022	License Action

2022-000284	Violation of licensing regulation	Closed-Investigation	09/07/2022	Advisement Letter

END OF REPORT

STATE OF ALASKA

Department of Commerce, Community, and Economic Development
Professional Licensing

ALASKA BOARD OF PHARMACY

September 22 - 23, 2022 Meeting

Board Packet

Alaska Board of Pharmacy Roster

Board Member Name	Initial Appointment	Reappointed	Term End
Justin Ruffridge, PharmD	03/01/2020	03/01/2019	03/01/2024
Ashley Schaber, PharmD	07/01/2021		03/01/2024
James Henderson, RPh	03/01/2017	03/01/2017	03/01/2025
Leif Holm, PharmD	03/01/2015		03/01/2023
Ramsey Bell, RPh	03/01/2022		03/01/2026
Vacant (Public Member)			
Vacant (Public Member)			

Position	Name
Chair	Justin Ruffridge
Vice Chair	Ashley Schaber
CSAC Chair/Delegate	Justin Ruffridge
Secretary	James Henderson

Updated 03/24/2022

ALASKA BOARD OF PHARMACY MEETING

TENTATIVE AGENDA

SEPTEMBER 23, 2022 – DAY 2

Dial: 839 3607 3617
Passcode: 960860

Discussion of the following topics may require executive session. Only authorized members will be permitted to remain in the Zoom room during executive session.

Board Members:

Justin Ruffridge, *PharmD (Chair)*

Ashley Schaber, *PharmD (Vice Chair)*

James Henderson, *RPh (Secretary)*

Ramsey Bell, *RPh*

Vacant, *Public Member*

Vacant, *Public Member*

Staff:

Laura Carrillo *Executive Administrator*

Bradley Johnson *Occupational Licensing Examiner*

Vacant, *Occupational Licensing Examiner*

Upcoming Meetings:

Nov. 17-18, 2022
Anchorage

Meeting Details

Meeting Name: September 23, 2022 - Alaska Board of Pharmacy Meeting

Meeting Start Time: 9:00 AM AKDT

Meeting Start Date: 09/23/2022 (Friday)

Meeting End Time: 4:30 PM AKDT

Meeting End Date: 09/23/2022 (Friday)

Meeting Location: Zoom & Anchorage (TBD)

Meeting Registration Link:

https://us02web.zoom.us/meeting/register/tZckdO-oqTgsG9OKqbjnmAn0HWtv8gClqFja

Agenda

I. Agenda Item #1 – 9:00 a.m. Roll Call/Call to Order (Chair Ruffridge)
II. Agenda Item #2 – 9:02 a.m. Review/Approve Agenda (Chair Ruffridge)
III. Agenda Item #3 – 9:05 a.m. Ethics Disclosures (Chair Ruffridge)
IV. Agenda Item #4 – 9:10 a.m. Public Comment #3
V. Agenda Item #5 – 9:25 a.m. Regulations #2
VI. Agenda Item #6 – 11:30 a.m. Lunch
VII. Agenda Item #7 – 12:30 p.m. Regulations #3
VIII. Agenda Item #8 – 2:30 p.m. Statutes

Upcoming Meetings:

Nov. 17-18, 2022
Anchorage

IX. Agenda Item #9 – 3:45 p.m. EA Recruitment (Director Chambers)

X. Agenda Item #10 – 4:15 p.m. Administrative Update (Laura Carrillo)

a. Task List

b. Travel/conference/trainings

c. Schedule next meeting dates

XI. Agenda Item #11 – 4:30 p.m. Public Comment #4

XII. Agenda Item #12 – 4:45 p.m. Adjourn

Links

Board of Pharmacy Homepage: pharmacy.alaska.gov

Prescription Drug Monitoring Program State page: pdmp.alaska.gov

CONFIDENTIAL

ETHICS SUPERVISOR DETERMINATION FORM

(Board or Commission Member)

Board or Commission: _____

Member Disclosing Potential Ethics Violation: _____

I have determined that the situation described on the attached ethics disclosure form

- ☐ does or would violate AS 39.52.110 - .190. Identify applicable statute below.
- ☐ does not or would not violate AS 39.52.110 - .190.

_____
Signature of Designated Ethics Supervisor (Chair)

_____
Printed Name of Designated Ethics Supervisor

Date: _____

COMMENTS (Please attach a separate sheet for additional space):

Note: Disclosure Form must be attached. Under AS 39.52.220, if the chair or a majority of the board or commission, not including the disclosing member, determines that a violation of AS 39.52.110-39.52.190 will exist if the member participates, the member shall refrain from voting, deliberating, or participating in the matter. A member will not be liable under the Ethics Act for action in accordance with such a determination so long as the member has fully disclosed all facts reasonably necessary to the determination and the attorney general has not advised the member, chair, or board or commission that the action is a violation. Forward disclosures with determinations to the State Ethics Attorney as part of your quarterly report. Quarterly reports are submitted to Litigation Assistant, Opinions, Appeals & Ethics, Department of Law, 1031 W. 4th Avenue, Suite 200, Anchorage, AK 99501.

Revised 2012

WHO IS MY DESIGNATED ETHICS SUPERVISOR?

Every state public officer, employee or board or commission member, has a designated ethics supervisor.

Executive Agencies

The ethics supervisor for each agency is the Commissioner or a senior manager to whom the Commissioner has delegated the function. The current ethics supervisor for each agency is listed below. The ethics supervisor for a Commissioner is Shawn Henderson, Director of Administrative Services in the Office of Governor, by delegation from the Governor.

Boards and Commissions

The Chair of each board and commission serves as the ethics supervisor for the other members and any executive director. The ethics supervisor for the Chair is Shawn Henderson, Director of Administrative Services in the Office of Governor, by delegation from the Governor. If a board or commission employs staff, the executive director serves as the ethics supervisor for these employees.

Public Corporations

The Chair of the board serves as the ethics supervisor for the other members of the board and any executive director. The executive director is the ethics supervisor for employees of the corporation.

Office of the Governor

The ethics supervisor for the Governor and Lieutenant Governor is the Attorney General. By delegation from the Governor, the ethics supervisor for the staff of the offices of the Governor and Lieutenant Governor is Shawn Henderson, Director of Administrative Services.

University of Alaska

By delegation of the University President, the ethics supervisor for university employees is Associate General Counsel Andy Harrington.

EXECUTIVE BRANCH AGENCIES

Administration: Dave Donley, Deputy Commissioner

Commerce, Community & Economic Development: Amy Demboski, Assistant Commissioner

Corrections: April Wilkerson, Administrative Services Director

Education & Early Development: Bobi Jo Grimes, HR Consultant III

Environmental Conservation: Theresa Zimmerman, Human Resources Manager

Fish & Game: Samantha Gatton, Acting Admin Services Director

Health & Social Services: Kimberley King, Human Resource Manager

Labor & Workforce Development: Cathy Muñoz, Deputy Commissioner

Law: Maria Bahr, Assistant Attorney General

Military & Veterans Affairs: Stanley A. Wright, Special Assistant to the Commissioner

Natural Resources: Peter Caltagirone, Special Assistant

Public Safety: Kelly Howell, Special Assistant to the Commissioner

Revenue: Brad Ewing, Administrative Services Director

Transportation & Public Facilities:

- Facility Services: John Binder, Deputy Commissioner
- Aviation: John Binder, Deputy Commissioner
- Central Region: Wolfgang Junge, Regional Director
- Northern Region: Rob Carpenter, Regional Director
- Southcoast Region: Lance Mearig, Regional Director
- Alaska Marine Highway System: Rob Carpenter, Deputy Commissioner
- Headquarters: Rob Carpenter, Deputy Commissioner
    - Administrative Services Division
    - Division of Program Development
    - Information Systems and Services Division
    - Statewide Design and Engineering Services Division

Updated June 2020

ETHICS INFORMATION FOR MEMBERS OF BOARDS & COMMISSIONS (AS 39.52)

Introduction

This is an introduction to AS 39.52, the *Alaska Executive Branch Ethics Act*. This guide is not a substitute for reading the law and its regulations. State board and commission members who have further questions should contact their board chair or staff.

The Ethics Act applies to all current and former executive branch public employees and *members of statutorily created boards and commissions*.

Scope of Ethics Act (AS 39.52.110)

Service on a state board or commission is a public trust. The Ethics Act prohibits substantial and material conflicts of interest. Further, board or commission members, and their immediate family, may not improperly benefit, financially or personally, from their actions as board or commission members. The Act does not, however, discourage independent pursuits, and it recognizes that minor and inconsequential conflicts of interest are unavoidable.

Misuse of Official Position (AS 39.52.120)

Members of boards or commissions may not use their positions for personal gain or to give an unwarranted benefit or treatment to any person. For example, board members may not:

- use their official positions to secure employment or contracts;
- accept compensation from anyone other than the State for performing official duties;
- use State time, equipment, property or facilities for their own personal or financial benefit or for partisan political purposes;
- take or withhold official action on a matter in which they have a personal or financial interest; or
- coerce subordinates for their personal or financial benefit.
- attempt to influence outcome of an administrative hearing by privately contacting the hearing officer.


Terry knew that a proposal that was before the board would harm Terry's business competitor. Instead of publicly disclosing the matter and requesting recusal, Terry voted on the proposal.


Board member Mick has board staff employee Bob type an article for him that Mick hopes to sell to an Alaskan magazine. Bob types the article on State time.

Improper Gifts (AS 39.52.130)

A board member may not solicit or accept gifts if a person could reasonably infer from the circumstances that the gift is intended to influence the board member's action or judgment. "Gifts" include money, items of value, services, loans, travel, entertainment, hospitality, and employment. All gifts from registered lobbyists are presumed to be improper, unless the giver is immediate family of the person receiving the gift.

A gift worth more than $150 to a board member or the board member's immediate family must be reported within 30 days if:

- the board member can take official action that can affect the giver, or
- the gift is given to the board member because he or she is on a state board.

The receipt of a gift worth less than $150 may be prohibited if a person could reasonably infer from the circumstances that the gift is intended to influence the board member's action or judgment. Receipt of such a gift should be disclosed.

Any gift received from another government, regardless of value, must be reported; the board member will be advised as to the disposition of this gift.

A form for reporting gifts is available at www.law.alaska.gov/doclibrary/ethics or from the board or commission staff.

This restriction on gifts does not apply to lawful campaign contributions.


The commission is reviewing Roy's proposal for an expansion of his business. Roy invites all the board members out to dinner at an expensive restaurant. He says it will be okay, since he isn't excluding any of the members.


Jody receives a holiday gift every year from Sam. Jody was recently appointed to a state board, but Sam has no business that is before the board. Jody may accept the gift.

Improper Use or Disclosure of Information (AS 39.52.140)

No former or current member of a board may use or disclose any information acquired from participation on the board if that use or disclosure could result in a financial or personal benefit to the board member (or immediate family), unless that information has already been disseminated to the public. Board members are also prohibited from disclosing confidential information, unless authorized to do so.

 Sheila has been on the board for several years. She feels she has learned a great deal of general information about how to have a successful business venture. So she sets up her own business and does well.

 Delores has always advised and assisted the other doctors in her clinic on their continuing education requirements. After Delores is appointed to the medical board, she discloses this role to the board and continues to advise the doctors in her clinic.

 Jim reviews a confidential investigation report in a licensing matter. He discusses the practitioner's violation with a colleague who is not a board member.

Improper Influence in State Grants, Contracts, Leases or Loans (AS 39.52.150)

A board member, or immediate family, may not apply for, or have an interest in a State grant, contract, lease, or loan, if the board awards or takes action to administer the State grant, contract, lease, or loan.

A board member (or immediate family) may apply for or be a party to a *competitively solicited* State grant, contract or lease, if the board as a body does not award or administer the grant, contract, or lease and so long as the board member does not take official action regarding the grant, contract, or lease.

A board member (or immediate family) may apply for and receive a State loan that is generally available to the public and has fixed eligibility standards, so long as the board member does not take (or withhold) official action affecting the loan's award or administration.

Board members must report to the board chair any personal or financial interest (or that of immediate family) in a State grant, contract, lease or loan that is awarded or administered by the agency the board member serves. *A form for this purpose is available at www.law.alaska.gov/doclibrary/ethics or from the board or commission staff.*

 John sits on a board that awards state grants. John hasn't seen his daughter for nearly ten years so he figures that it doesn't matter when her grant application comes up before the board.

 The board wants to contract out for an analysis of the board's decisions over the last ten years. Board member Kim would like the contract since she has been on the board for ten years and feels she could do a good job.

Improper Representation (AS 39.52.160)

A board or commission member may not represent, advise, or assist a person in matters pending before the board or commission for compensation A nonsalaried board or commission member may represent, advise, or assist in matters in which the member has an interest that is regulated by the member's own board or commission, if the member acts in accordance with AS 39.52.220 by disclosing the involvement in writing and on the public record, and refraining from all participation and voting on the matter. This section does not allow a board member to engage in any conduct that would violate a different section of the Ethics Act.

 Susan sits on the licensing board for her own profession. She will represent herself and her business partner in a licensing matter. She discloses this situation to the board and refrains from participation in the board's discussions and determinations regarding the matter.

Restriction on Employment After Leaving State Service (AS 39.52.180)

For two years after leaving a board, a former board member may not provide advice or work for compensation on any matter in which the former member personally and substantially participated while serving on the board. This prohibition applies to cases, proceedings, applications, contracts, legislative bills, regulations, and similar matters. This section does not prohibit a State agency from contracting directly with a former board member.

With the approval of the Attorney General, the board chair may waive the above prohibition if a determination is made that the public interest is not jeopardized.

Former members of the governing boards of public corporations and former members of boards and commissions that have regulation-adoption authority, except those covered by the centralized licensing provisions of AS 08.01, may not lobby for pay for one year.

 The board has arranged for an extensive study of the effects of the Department's programs. Andy, a board member, did most of the liaison work with the contractor selected by the board, including some negotiations about the scope of the study. Andy quits the board and goes to work for the contractor, working on the study of the effects of the Department's programs.

 Andy takes the job, but specifies that he will have to work on another project.

Aiding a Violation Prohibited (AS 39.52.190)

Aiding another public officer to violate the Ethics Act is prohibited.

Agency Policies (AS 39.52.920)

Subject to the Attorney General's review, a board may adopt additional written policies further limiting personal or financial interests of board members.

Disclosure Procedures

DECLARATION OF POTENTIAL VIOLATIONS BY MEMBERS OF BOARDS OR COMMISSIONS (AS 39.52.220)

A board member whose interests or activities could result in a violation of the Ethics Act if the member participates in board action must disclose the matter on the public record and in writing to the board chair who determines whether a violation exists. *A form for this purpose is available at www.law.alaska.gov/doclibrary/ethics or from the board or commission staff*. If another board member objects to the chair's ruling or if the chair discloses a potential conflict, the board members at the meeting (excluding the involved member) vote on the matter. If the chair or the board determines a violation will occur, the member must refrain from deliberating, voting, or participating in the matter. For more information, see *Ethics Act Procedures for Boards and Commissions* available at the above noted web site.

When determining whether a board member's involvement in a matter may violate the Ethics Act, either the chair or the board or commission itself may request guidance from the Attorney General.

ATTORNEY GENERAL'S ADVICE (AS 39.52.240-250)

A board chair or a board itself may request a written advisory opinion from the Attorney General interpreting the Ethics Act. A former board member may also request a written advice from the Attorney General. These opinions are confidential. Versions of opinions without identifying information may be made available to the public.

REPORTS BY THIRD PARTIES (AS 39.52.230)

A third party may report a suspected violation of the Ethics Act by a board member in writing and under oath to the chair of a board or commission. The chair will give a copy to the board member and to the Attorney General and review the report to determine whether a violation may or does exist. If the chair determines a violation exists, the board member will be asked to refrain from deliberating, voting, or participating in the matter.

Complaints, Hearings, and Enforcement

COMPLAINTS (AS 39.52.310-330)

Any person may file a complaint with the Attorney General about the conduct of a current or former board member. Complaints must be written and signed under oath. The Attorney General may also initiate complaints based on information provided by a board. A copy of the complaint will be sent to the board member who is the subject of the complaint and to the Personnel Board.

All complaints are reviewed by the Attorney General. If the Attorney General determines that the complaint does not warrant investigation, the complainant and the board member will be notified of

the dismissal. The Attorney General may refer a complaint to the board member's chair for resolution.

After investigation, the Attorney General may dismiss a complaint for lack of probable cause to believe a violation occurred or recommend corrective action. The complainant and board member will be promptly notified of this decision.

Alternatively, if probable cause exists, the Attorney General may initiate a formal proceeding by serving the board or commission member with an accusation alleging a violation of the Ethics Act. Complaints or accusations may also be resolved by settlement with the subject.

CONFIDENTIALITY (AS 39.52.340)

Complaints and investigations prior to formal proceedings are confidential. If the Attorney General finds evidence of probable criminal activity, the appropriate law enforcement agency shall be notified.

HEARINGS (AS 39.52.350-360)

An accusation by the Attorney General of an alleged violation may result in a hearing. An administrative law judge from the state's Office of Administrative Hearings serves as hearing officer and determines the time, place and other matters. The parties to the proceeding are the Attorney General, acting as prosecutor, and the accused public officer, who may be represented by an attorney. Within 30 days after the hearing, the hearing officer files a report with the Personnel Board and provides a copy to the parties.

PERSONNEL BOARD ACTION (AS 39.52.370)

The Personnel Board reviews the hearing officer's report and is responsible for determining whether a violation occurred and for imposing penalties. An appeal may be filed by the board member in the Superior Court.

PENALTIES (AS 39.52.410-460)

When the Personnel Board determines a board member has violated the Ethics Act, it will order the member to refrain from voting, deliberating, or participating in the matter. The Personnel Board may also order restitution and may recommend that the board member be removed from the board or commission. If a recommendation of removal is made, the appointing authority will immediately remove the member.

If the Personnel Board finds that a former board member violated the Ethics Act, it will issue a public statement about the case and will ask the Attorney General to pursue appropriate additional legal remedies.

State grants, contracts, and leases awarded in violation of the Ethics Act are voidable. Loans given in violation of the Ethics Act may be made immediately payable.

Fees, gifts, or compensation received in violation of the Ethics Act may be recovered by the Attorney General.

The Personnel Board may impose a fine of up to $5,000 for each violation of the Ethics Act. In addition, a board member may be required to pay up to twice the financial benefit received in violation of the Ethics Act.

Criminal penalties are in addition to the civil penalties listed above.

DEFINITIONS (AS 39.52.960)

Please keep the following definitions in mind:

Benefit - anything that is to a person's advantage regardless financial interest or from which a person hopes to gain in any way.

Board or Commission - a board, commission, authority, or board of directors of a public or quasi-public corporation, established by statute in the executive branch, including the Alaska Railroad Corporation.

Designated Ethics Supervisor - the chair or acting chair of the board or commission for all board or commission members and for executive directors; for staff members, the executive director is the designated ethics supervisor.

Financial Interest - any property, ownership, management, professional, or private interest from which a board or commission member or the board or commission member's immediate family receives or expects to receive a financial benefit. Holding a position in a business, such as officer, director, partner, or employee, also creates a financial interest in a business.

Immediate Family - spouse; another person cohabiting with the person in a conjugal relationship that is not a legal marriage; a child, including a stepchild and an adoptive child; a parent, sibling, grandparent, aunt, or uncle of the person; and a parent or sibling of the person's spouse.

Official Action - advice, participation, or assistance, including, for example, a recommendation, decision, approval, disapproval, vote, or other similar action, including inaction, by a public officer.

Personal Interest - the interest or involvement of a board or commission member (or immediate family) in any organization or political party from which a person or organization receives a benefit.

For further information and disclosure forms, visit our Executive Branch Ethics web site or please contact:

State Ethics Attorney
Alaska Department of Law
1031 West 4th Avenue, Suite 200
Anchorage, Alaska 99501-5903
(907) 269-5100
attorney.general@alaska.gov

Revised 9/2013

EXECUTIVE BRANCH ETHICS ACT

Responsibilities of Designated Ethics Supervisors for Boards and Commissions

Boards and commissions subject to the Ethics Act have designated ethics supervisors. The chair serves as the designated ethics supervisor for board or commission members and the executive director. The executive director is the designated ethics supervisor for staff. The designated ethics supervisor for a chair is the governor, who has delegated this responsibility to Guy Bell, Administrative Director of the Office of the Governor.

Designated ethics supervisors should refer to the **2019 Designated Ethics Supervisors Handbook** (503KB PDF), available from the state ethics attorney, regarding their responsibilities under the Ethics Act. Briefly, as designated ethics supervisor, you must --

1. Ensure that members and employees are provided copies of the guides, Ethics Information for Members of Boards and Commissions and Ethics Act Procedures for Boards and Commissions -- and keep a supply of disclosure forms.
    1. These guides, other educational materials, disclosure forms, statutes and regulations are available for review and copying on the Department of Law ethics web site. If access to this page is not available, please contact the Attorney General's office at 269-5275.
2. Review all disclosures, investigate potential ethics violations, make determinations regarding conduct, and take action.
3. Keep member or employee disclosure statements (of potential violations, receipt of gifts, and interests in grants/contracts/leases/loans) on file in your office. Disclosure of a gift received from another government must be forwarded to the Office of the Governor.
4. Submit an ethics report to the Department of Law in April, July, October and January for the preceding quarter. You will receive a reminder. There is a sample report on the ethics web page.
    1. Mail, email or fax to Jennifer L. Williams, Paralegal, Department of Law, Opinions, Appeals & Ethics Section, 1031 W. 4th Avenue, Suite 200, Anchorage, AK, 99501, ethicsreporting@alaska.gov, fax no. 907-258-4978.

You may request ethics advice from your agency's Assistant Attorney General or from the State Ethics Attorney, Maria Bahr, at 269-5285 or maria.bahr@alaska.gov. Please direct questions about reporting procedures to Jennifer L. Williams at 269-5275 or jennifer.williams1@alaska.gov.

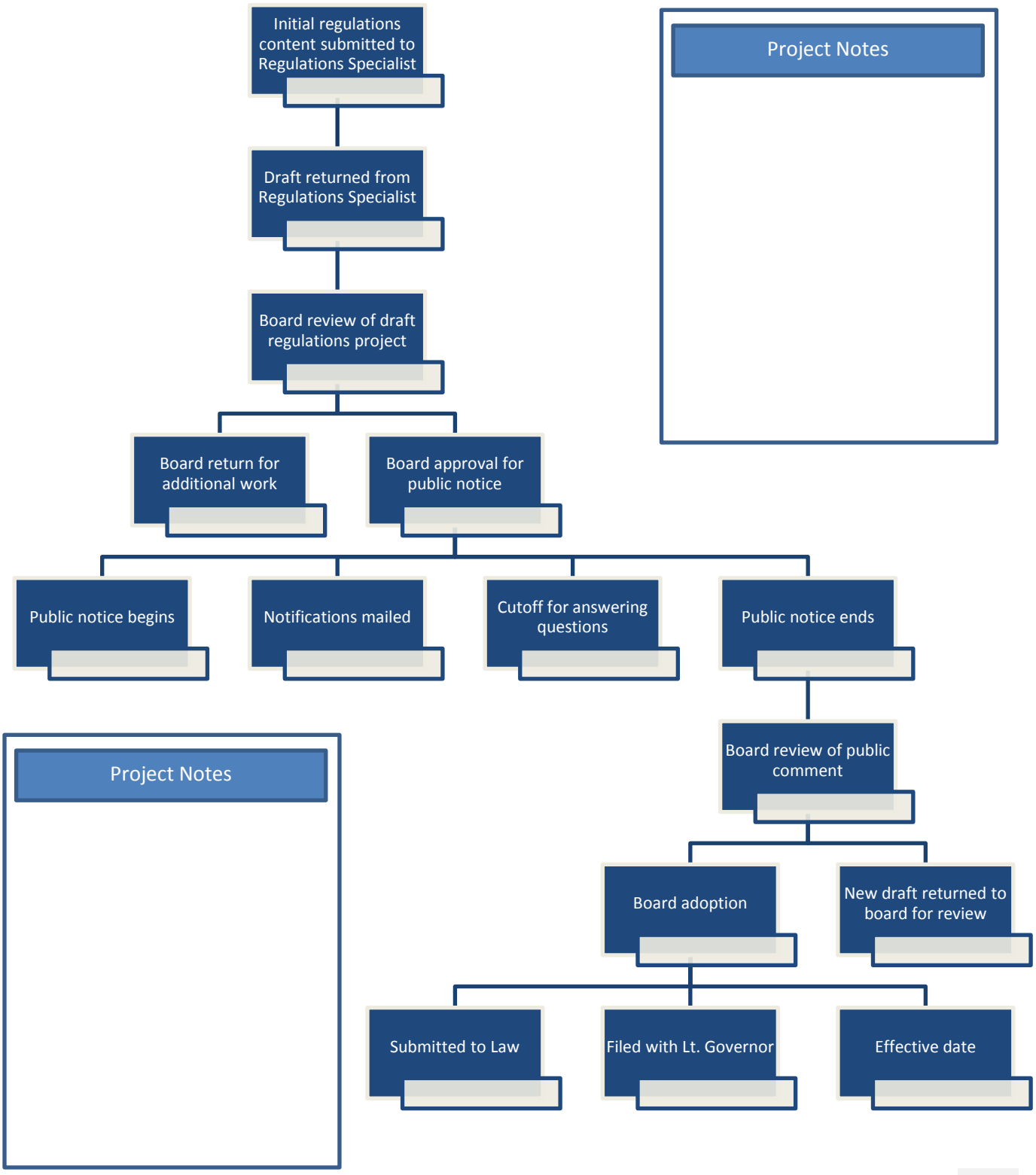
6/19

Regulations Project Tracker

☐ CBPL ☐ Board: _____

General topic of regulations: _____

Regulations being amended: 12 AAC _____



Steps in the Board Regulation Adoption Process

Day 1

1

At an open meeting, the board votes on language to change regulations. This motion is forwarded to the Division Regulations Specialist for drafting.

Day 30

2

Once drafting is complete, the board holds another public meeting to edit or approve draft for public notice.

3

Approved language is reviewed by Division attorney.

4

Department of Law opens file.

5

Day 45

Division publishes and distributes public notice, additional regulation notice information, and proposed regulation to all licensees and interested parties. Public notice posted in newspaper and on Alaska Online Public Notice System

6

Public comment period and/or hearing (if applicable).

Day 65

7

Division Regulations Specialist compiles answers to questions and posts FAQ on the program web page.

Day 75

8

Regulations Specialist compiles public comments for distribution to board.

Day 90

9

Board holds an open meeting to review public comments, make minor changes, and adopt regulations. Substantive changes may require additional drafting and public notice (Step 2).

10

Division submits final regulation package to Department of Law for review and approval, and to the Governor's office.

11

Agency attorney reviews regulation

12

Regulations attorney reviews and either approves or disapproves regulation

Day 110

13

Unless returned by the Governor, Lt. Governor's office files approved regulation; regulations become effective in 30 days

Day 150

.

Once Regulations Are Effective

14a

Agency posts summary on Alaska Online Public Notice System

14b

Regulation published in Alaska Administrative Code

14c

Forms & FAQ updated on program web page

All timeframes are estimated, dependent upon staff and attorney workflow and board scheduling.

Steps in the Regulation Process for a Board and Commission (board)[1]

Beginning the Process

1. At an open meeting, the board initiates and votes on proposed regulation changes.

2. **Reason:** Identify the reason for the proposed action, such as compliance with new or changed state law. If applicable, identify the law, order, decision, or other action of the federal government, or federal or state court, if that is the basis for the proposed action. The description need only be a sentence or two.

3. **Cost information:** In the meeting minutes there must be estimated costs in the aggregate to comply with the proposed action to:

    - A private person
    - Another state agency
    - A municipality

    Cost information is described simply as an estimate of annual costs within the board's ability to determine due to its familiarity with the regulated community.

    Example: The Board of Chiropractic Examiners is proposing to add three CE credits to their continuing competency requirements for a biennial license renewal. The proposal may cost

    - A private person: $50 per applicant/licensee
    - Another state agency: None known
    - A municipality: None known

4. Within 10 days of the meeting, board staff must transmit board minutes[2] or an excerpt of the minutes, draft language or proposals, and a completed Regulations FAQ Worksheet for the proposed regulation changes requested by the board to the Regulations Specialist.

What comes next: Regulations Specialist

5. The Regulations Specialist determines if there is authority in statute to adopt the proposed regulation changes.

6. The Regulations Specialist prepares a draft of regulation changes, using the Department of Law's *Drafting Manual for Administrative Regulations* for conformity and style, and works with board staff before submitting the final draft to the board for review/approval. In some instances the draft regulation changes will be reviewed by an AAG before the final draft is submitted to the board for review/approval.

7. Once completed, the draft proposed regulation changes are presented to the board at its next public meeting to review and approve the final draft, amends if needed, and requests that the approved draft be finalized and public noticed.

Public Notice

8. NOTE: The board must **always** provide an opportunity for submission of written comments in the regulation-adoption process. Also, the board should determine if it wants to hold a public hearing on the proposed regulation changes at its next meeting. If it does, the location, date and time of the hearing needs to be included in the public notice. Public hearings are usually held in conjunction with a regularly-scheduled meeting of the board and are always recorded. Oral public hearing is optional; however, answering the following questions will help the board determine if an oral public hearing is needed:

    - Are the regulations controversial and is there likely to be substantial public interest in them?
    - Would those most affected by the regulations be better able to participate if an oral hearing were held?
    - Would the board benefit from a face-to-face or teleconferenced opportunity to receive comments on the proposed regulations from interested persons?

9. Regulations Specialist sends notice to Alaska Dispatch News (or other newspapers if warranted) for publication, all interested parties, and licensees, if warranted. The Regulations Specialist posts the notice on the Alaska Online Public Notice System, electronically transmits a copy of the notice and proposed regulation changes to all incumbent legislators and the Legislative Affairs Agency, House & Senate Labor & Commerce Committees, Legislative Council, Lt. Governor, Governor, and Department of Law (Law). It is also emailed to board members and affected staff, including the commissioner's office. Public notice will be posted on the board's webpage.

Comment Period

10. The Regulations Specialist or board staff shall make a good faith effort to answer relevant questions received at least 10 days before the end of the public comment period. Questions must be in writing or asked at the legally noticed public meeting. The Regulations Specialist or board staff shall answer questions in writing and make the questions and answers available on the Alaska Online Public Notice System and the board's webpage. FAQs will be posted on the board's webpage and updated when relevant questions are answered. The Regulations Specialist or board staff may, but are not required to, answer written questions received after the 10-day cutoff date.

11. After the comment deadline (at least 30 days in duration), comments received on proposed regulation changes are compiled and copied by the Regulations Specialist and given to board staff to include in the board packets for the next open board meeting to be considered prior to adopting. Comments received after the deadline should not be forwarded to the board and comments should not be taken at the board meeting from the public prior to adoption unless a hearing was noticed and the comments are heard by the board during the comment period.

Adoption

12. The board's options regarding the proposed regulation changes at its next meeting are:

a. It can adopt the proposed regulation changes as written/publicly noticed, amend, and adopt them; or
b. Choose to take no action on them.
c. Substantive changes may require additional drafting and public notice (**see** Step 7 above).

13. When making a motion to adopt the regulations, the board is required to state on the record that it has reviewed any comments received, and considered the cost to private persons of the regulatory action being taken.

14. When regulation changes are adopted:

a. The chair signs the adoption/certification order; and
b. The board staff signs an affidavit of board action and/or affidavit of oral hearing (if applicable) and attaches it to the relevant minutes or an excerpt of the minutes and forwards to the Regulations Specialist.

Finalizing the regulation change process

15. Regulations Specialist prepares the final regulation package for transmittal to Department of Law for final review/approval, which includes the adopted regulations, certain affidavits, and other appropriate documents.

16. Assigned agency attorney reviews the regulations.

17. Regulations attorney reviews and either approves or disapproves regulation changes. Law reviews and will occasionally make edits. (On rare occasions, this may require the edited version to be re-adopted by the board at a subsequent meeting.) At the same time, the adopted regulations are submitted to the governor for review. The governor has 30 days to review the regulations under AS 44.62.040(c), and return the regulation for specified reasons.

18. Unless returned by the governor, when the governor and Law's review are complete, the adopted regulations are forwarded to the Lt. Governor for filing. Regulation changes are effective 30 days after filing unless a later effective date is specified in the adoption order.

Once regulations are effective

19. Agency posts summary of approved regulation changes on Alaska Online Public Notice System.

20. Agency updates statutes and regulations board webpage.

21. Regulation published in Alaska Administrative Code.

[1] The process may take six months to a year or longer to complete. It may be expedited if a board meets often or holds a teleconference following the written comment period to adopt the final regulations. Department of Law workload also plays a big part in the timeframe.

[2] Board minutes reflecting concisely what the project entails plays an important part in getting a project rolling. This is true for the initial stages and the final motion adopting the regulations following the public comment period due to the relevant minutes or an excerpt of the minutes being forwarded to the Department of Law with the final project.

Regulation Changes Questionnaire

Division/Board: _____ Meeting Date:_____

Regulation change being proposed: 12 AAC_____

General topic of the regulation: _____

This worksheet is designed to help the board think through an anticipated regulations project. Staff will provide this worksheet to the board at the time a regulations project is being approved for public notice. This information will be used to develop a FAQ to be posted on the board's web page to help the public understand the project. Staff will submit the completed worksheet with the draft board minutes to the Regulations Specialist within 10 days of the meeting and provide a copy to the supervisor. Appropriate staff will be assigned to complete this worksheet if a division regulation. **NOTE:** ***Use a separate worksheet for each section being proposed.***

1. Is the new regulation needed to comply with new legislation or federal law?	Yes ☐ No ☐
If yes, effective date of new statute/federal law: _____	
(If appropriate, ensure the new regulation is in line with federal requirements prior to initiating a regulation project.)	
2. Does the change add a new license type?	Yes ☐ No ☐
If yes:	
Does it affect current licensees?	Yes ☐ No ☐
Do current licensees/non-licensees already perform the service for which the new license type is required?	Yes ☐ No ☐
Is there a grace period or date explicitly included in the regulation to allow for a transition period?	Yes ☐ No ☐
3. Does it change the qualifications or requirements of an existing license?	Yes ☐ No ☐
If yes, does it affect current licensees?	Yes ☐ No ☐
4. Does it affect continuing education/competency requirements?	Yes ☐ No ☐
If yes:	
Does it add additional requirements or hours?	Yes ☐ No ☐
Does it clarify existing regulations?	Yes ☐ No ☐
Is there an effective date in the future to give licensees time to comply?	Yes ☐ No ☐
5. Is it a fee change or does it create a new fee?	Yes ☐ No ☐
If yes:	
Does it move fees in the centralized regulations to a new number, therefore affecting other program regulations?	Yes ☐ No ☐
6. Does it make changes to the requirements of licensees?	Yes ☐ No ☐
If yes:	
All licensees	Yes ☐ No ☐
Certain licensees (List: _____)	Yes ☐ No ☐
Initial licensees	Yes ☐ No ☐
7. In addition to interested parties, who should receive the public notice? (All licensees or certain license types?)	

8. In addition to the 30-day minimum written notice, does the board request a public hearing? If yes, when and where.
9. What will the regulation do?
10. What is the demonstrated public need or purpose of this regulation?
11. What is the known or estimated cost of the new regulation to a private person, another agency, or a municipality (see Step 3 of the *Steps in the Regulation Process…*)?
12. What positive consequences may this regulation have on public or private people, businesses, or organizations?
13. What negative consequences may this regulation have on public or private people, business, or organizations?
14. If any negative consequences, please address the reasons why the public need for this change outweighs the negative impact.
15. List any additional questions or comments that may arise from the public during the comment period. Include a response to the questions.
16. What type of notification outlining the changes will be required once the regulation is adopted? Check appropriate boxes. FAQ on website ☐ Email to licensees ☐ *Letter to licensees ☐ * *Cost to board for mailing letter*

Staff submitting this worksheet: _____ Date submitted to Regulations Specialist: _____

VI. Effective Regulations

This section is intended to provide you with a general overview of the regulations process. It is not legal guidance; the applicable statutes control. Any legal questions should be addressed to the Department of Law.

Regulations must be based on statutory authority. Within the division, regulations typically clarify the requirements of the occupational licensing program as set forth by the Alaska State Legislature in statute. As mentioned in the beginning of this manual, statutes are state laws that authorize and set out the scope of a board or commission's governance authority of a licensing program. Statutes may also authorize and direct the division's management role in all licensing programs overseen by the division. Where statutes assign to a board the responsibility of adopting regulations, that board must follow the process set forth in the Administrative Procedure Act (APA) (AS 44.62.010–44.62.305) unless the legislature has by statute directed a board or commission to follow another process. The APA's requirements are explained in detail in the *Drafting Manual for Administrative Regulations.* The Drafting Manual is at http://law.alaska.gov/doclibrary/drafting_manual.html.

State agencies subject to the APA must follow the statutory procedures in order to adopt, amend, or repeal a regulation. A significant step in the APA requires that the public receive notice of a proposed regulation and an opportunity to comment on a proposed regulatory action. This ensures that the public and interested parties—predominantly licensees and prospective licensees—are aware of the proposed changes affecting their programs and provides adequate opportunity to comment on them. By ensuring public notice and ability to comment, the APA's procedures support the public's vital role in the regulations process.

Overview of the Regulations Process

When a board identifies the need to propose a regulation to implement, interpret or make specific a state statute, the board, it should begin organizing its collective thoughts on the matter, at a publicly noticed meeting. If the subject matter is highly technical or complex, it may be helpful for the board to form a working group from among its members. That group may engage in fact-finding outside of public meetings, for the purpose of sharing its findings with the entire board at an appropriate meeting.

The maker of the motion to propose amendment, adoption, or repeal of regulations should provide the board with a written draft of the proposal. It is the board's responsibility to be certain that the record reflects what the board intended. This means that the board should articulate what it is hoping to accomplish with the project, and it should carefully review written drafts, to ensure that the language conveys what the board intended. It is the board's job to provide at least the initial draft of language for a proposed regulation or amendment to regulation. Some boards find it helpful to request assistance from their staff, executive director, and the department's regulations specialist.

Under the APA, the public must have a minimum of 30 days to comment (either orally or in writing, or both) on proposed regulations. During the comment period, the staff must publish on the website answers to questions from the public on the proposed regulations received in writing unless the questions are received within 10 days before the close of the comment period; in that case the staff may, but is not required to, answer the questions. The board will meet either telephonically or in person after this period closes to review written comments and amend or adopt the proposal. A board may also notice a meeting at which oral testimony may be heard on the proposal.

If the board chooses to substantially amend its proposal, it must go out for another 30-day public comment period. Whether the amendments to the proposed regulations would require a new notice and comment period should be reviewed by the Department of Law. If the changes are minor and do not alter the meaning of the regulations, it may then be forwarded for review by the Department of Law.

The Department of Law will assign an agency attorney who is familiar with licensing issues to review the proposal for content. Once the agency attorney review is complete, either the regulations attorney or the assistant regulations attorney will review for legality, consistency with other provisions of law and conformance to the state's drafting style. If there are questions, the regulations attorneys will contact the agency attorney. Once the regulations have been approved by the regulations attorney in the Department of Law, the regulations are transmitted to the Office of the Lieutenant Governor for filing. Once signed by the Lieutenant Governor or the Lieutenant Governor's designee, his/her designee, the regulation will become effective in 30 days *unless* another effective date is specified in the adoption order or certification of adoption.

A typical board or commission regulations process can take 90-180 days, depending on the workload of the division Regulations Specialist, the complexity of the project, and scheduling a review with the Department of Law.

Due to Alaska's small population, Board members may be easily accessible to their licensees and public stakeholders. Board members must remember that comments on proposed regulations must be received as requested in the notice of proposed regulations. Comments may only be received on proposed regulations by -

Written comments that are received by the division Regulations Specialist during the public comment period as set out in the notice of proposed regulations, oral comments that are received by the board during the public comment period noticed on the state Online Public Notice System

Board members may not receive comments directly via email, text, in the grocery store, at the lodge, in the hair salon, or on the golf course. When well-meaning members of the public offers input, thank them for their interest but remind them that you are only one of several board members and the board can only act as one; therefore, they should submit their comment as directed in the public notice.

The Division Director may also draft and notice regulations through the same process, though there may not be a public meeting to deliberate or adopt final regulations. The same public notice provisions apply, and the Director must consider all written comments received. When setting fees for licensing programs, the Director will seek board input on proposed fees as required in AS 08.01.065. The Director may adopt regulations that pertain to all licensing programs in general (known as Centralized Regulations) and may adopt regulations that direct the licensing programs in AS 08.01 that do not have a governing board or commission.

Where to Seek Help

The division Regulations Specialist II is trained to assist in drafting regulations and moving them through the adoption process. The Division Director, Division Operations Manager, or Executive Administrator should also be able to walk the board through the process of adopting regulations. They may also request attorney advice independently or on behalf of the board. The flow charts that follow should clarify the processes of board and division regulation adoption, though the process is ultimately administered by the Department of Law.

Is It A Regulation Or Policy?

REGULATIONS

- Anything that affects the public or is used by the agency in dealing with the public;
- Have the force and effect of law;
- Licensees must follow them;
- Prospective licensees must comply with them in order to be licensed;
- Can only be created by following the process outlined in the Administrative Procedure Act – AS 44.62;
- This process can be time-consuming, taking months or years. It involves at a minimum:
    - 30-day public notice,
    - Review by Department of Law, and,
    - Can't be changed, except by formal process.

POLICIES, ADVISORIES, AND GUIDELINES

- Anything a regulatory boards says that:
    - Sets out the regulatory board's expectations in general, nonbinding terms,
    - Does not have the force and effect of law.

- Disciplinary Matrix is a *guideline* if it is used as a reference point, along with:

- Careful consideration of facts and circumstances, as well as,
- Underlying goals of the statute and purpose for the discipline.

- Disciplinary Matrix is a *regulation* if it is used:
  - As a formula: *"If licensee did X, then disciplinary response = Y."*
  - To achieve or demonstrate consistency by showing how the board will respond in every case where certain facts are present: *"All licensees who do X get Y."*

GENERAL PRINCIPLES APPLICABLE TO BOTH REGULATIONS AND POLICIES

- Clarity
  - If it affects licensees or the public, it should be available and understandable. *Ex.:* if the board keeps a list of activities that it will approve as uncompensated professional activities under 12 AAC 44 620((a)(2)(E), the list should be accessible on the board's website.

- Consistency
  - With other communications about similar facts;
  - With the governing statute's purpose.
  - Proportionality
    - License denials and disciplinary actions including suspension, revocations, and fines should be consistent with the statute's goals.

Steps in the Board Regulation Adoption Process

Day 1

1

At an open meeting, the board votes on language to change regulations. This motion is forwarded to the Division Regulations Specialist for drafting.

Day 30

2

Once drafting is complete, the board holds another public meeting to edit or approve draft for public notice.

3

Approved language is reviewed by Division attorney.

4

Department of Law opens file.

5

Day 45

Division publishes and distributes public notice, additional regulation notice information, and proposed regulation to all licensees and interested parties. Public notice posted in newspaper and on Alaska Online Public Notice System

6

Public comment period and/or hearing (if applicable).

Day 65

7

Division Regulations Specialist compiles answers to questions and posts FAQ on the program web page.

Day 75

8

Regulations Specialist compiles public comments for distribution to board.

Day 90

9

Board holds an open meeting to review public comments, make minor changes, and adopt regulations. Substantive changes may require additional drafting and public notice (Step 2).

10

Division submits final regulation package to Department of Law for review and approval, and to the Governor's office.

11

Agency attorney reviews regulation

12

Regulations attorney reviews and either approves or disapproves regulation

Day 110

13

Unless returned by the Governor, Lt. Governor's office files approved regulation; regulations become effective in 30 days

Day 150

.

Once Regulations Are Effective

14a

Agency posts summary on Alaska Online Public Notice System

14b

Regulation published in Alaska Administrative Code

14c

Forms & FAQ updated on program web page

All timeframes are estimated, dependent upon staff and attorney workflow and board scheduling.

Legislative Recommendations - Proposed Legislation for FY 2023

☐ **No Recommendations**
The Board has no recommendations for proposed legislation at this time.

☒ **Recommendations**
The Board has the following recommendations for proposed legislation:

With the passage of HB 145 in FY2022 that overlap with changes the Board of Pharmacy previously identified in its FY2021 legislative recommendations, a number of intended statutory changes will be resolved. Common interest areas covered in HB 145 and to be effective 90 days subsequent to Governor Dunleavy's signature, include:

- Removal of “dosage form” from the definition of “equivalent drug product” in AS 08.80.480.
- Clarification of pharmacists’ ability to independently prescribe and administer vaccines and emergency medications under AS 08.80.168
- Expansion of pharmacist's ability to independent treat and monitor other conditions as needed
- Allowing pharmacist interns and pharmacy technicians, as supervised by a pharmacist, to prescribe vaccines and emergency medications under AS 08.80.168
- Recognition of pharmacists as providers under AS 21.36.090(d) to eliminate insurance reimbursement discrimination for services provided.

A summary of the Board of Pharmacy’s legislative recommendations it intends to pursue in FY2023 include:

Statutory area	Summary of Change	Citation
Moral character	Remove moral character requirement from applications for pharmacists via examination and reciprocity	AS 08.80.110(2), AS 08.80.145(3)
Registration of pharmacies	Repeal registration and introduce a licensure category	AS 08.80.158
Requirements for non-resident pharmacies	Include devices, require licensure	AS 08.80.159
Licenses not affected	Drug dispensing machines	AS 08.80.400
Prohibited terms	Add “apothecary”	AS 08.80.420
Powers and duties of the board	Regulate the practice of white and brown bagging; regulate kiosks as a separate license type	AS 08.80.030
Creation and membership of board; officers	Add a technician seat; remove one public member seat	AS 08.80.010
National criminal history record check	Require FBI fingerprints for pharmacist applicants	AS 12.62.400

Recommended amendments are include on the following page.

Legislative Recommendations (continued)

The Board of Pharmacy recommends REPEALING the following:

- AS 08.80.030(b)(10) - (Powers and Duties of the Board): "issue licenses to persons engaged in the manufacture and distribute of drugs and devices;"
- AS 08.80.110(2) - (Qualifications for Licensure by Examination): "furnish the board with at least two affidavits from reputable citizens that the applicant has known for at least one year attesting to the applicant's good moral character;"
- AS 08.80.145(3) - (Reciprocity; License Transfer): "is of good moral character"
- AS 08.80.145(5) - (Reciprocity; License Transfer): "or has met the internship requirements of this state"
- AS 08.80.160(10) - (Fees): "Registration or"

The Board of Pharmacy recommends AMENDING the following:

- AS 08.80.0310(a) - (Creation and Membership of Board; Officers): "There is created the Board of Pharmacy, composed of seven (or eight) members, five of whom shall be pharmacists licensed in the state
  who have been actively engaged in the practice of pharmacy in the state for a period of three years immediately preceding their appointment. One shall be a pharmacy technician licensed in the state for at least two years. One shall be a person with no direct final interest in the healthcare industry."
- AS 08.80.030(b)(14) - (Powers and Duties of the Board): "require that a licensed pharmacist dispensing federally-scheduled controlled substances in the state register with the controlled substance prescription database under AS 17.30200(o)"
- AS 08.80.030(b)(16) - (Powers and Duties of the Board): "license wholesale drug distributors, third-party logistics providers, outsourcing facilities, and manufacturers under AS 08.80.159, and pharmacies under AS 08.80.157 that are physically located outside the state"
- AS 08.80.159(a) - (Licensing and Inspection of Facilities Outside of the State): "Before shipping, mailing, mailing, distributing, or delivering prescription drugs to a licensee in the state or advertising in the state, a wholesale drug distributor, manufacturer, third-party logistics provider, or an outsourcing facility that is located outside of the state shall"
- AS 08.80.420(a) - (Certain Advertising Prohibited): "A person may not use or exhibit the title “pharmacist,” “assistant pharmacist,” or “druggist,” or the descriptive term “pharmacy,” “drug store,” “drug sundries,” “apothecary”, or other similar title or term containing the word “drug,” in any business premises, or in an advertisement through the media of press, or publication, or by radio or television, unless the business has a licensed pharmacist in regular and continuous employment."

The Board of Pharmacy recommends ADDING the following:

- AS 08.80.030(b)(17) - (Powers and Duties of the Board): "license and establish standards for automated prescription drug machines installed outside the premise of institutional facilities"
- AS 08.80.030(b)(18) - (Powers and Duties of the Board): "establish standards for the practice of white and brown bagging"
- AS 08.80.030(b)(19) - (Powers and Duties of the Board): "license Internet pharmacies providing services to residents in the State"

Task Status Key:

	Complete
	Pending
	Not started
	On hold per director/gov order

ALASKA BOARD OF PHARMACY
TASK LIST (ACTION ITEMS)

Action Items from June 16, 2022 Meeting (as of 06/24/2022)	
1	*Dr. Ruffridge will send the signed imposition of civil fines to Investigator Bowles.*
2	*Ms. Carrillo will distinguish between kiosks and automated dispensing cabinets in the annual report and will post the annual report to the board's website.*
3	*Ms. Carrillo will see whether defining "jurisdiction" is in statute or regulation. Language in law book seems to imply to applicants outside of Alaska but within the U.S.*
4	*Ms. Carrillo will post the FY 2023 Strategic Plan to the board's website.*
5	*Ms. Carrillo will notify emergency permit applicants that they do not qualify; instruct them to apply for permanent license.*
6	*Ms. Carrillo will process the pharmacy technician application for Marlene Rivas, 187538.*
7	*Ms. Carrillo will process the collaborative practice agreement for Providence Kodiak Island Medical Center.*
8	*Ms. Carrillo will request a legal opinion regarding jurisdiction of foreign applicants.*
9	*Ms. Carrillo will follow-up with Costco pharmacy #10, PHAR339, on employee CS theft.*
10	*Ms. Schaber and Ms. Sherrell will convene as part of the 42 CFR Part 2 Subcommittee.*
11	*Ms. Carrillo will follow-up with Dr. Neptune on crisis stabilization units to clarify what specific pharmacy services will be provided.*
12	*Ms. Carrillo will add technician and intern licenses/ability to expire license upon request with approval by the EA as a new regulation project for the September 2022 meeting; possible amendment to language requiring technician license to be returned.*
13	*Ms. Carrillo will coordinate with Ms. Dumas and regulations specialist, Jun Maiquis, on implementing manufacturer regulations concurrent with the new fees.*
14	*Ashley Schaber and Ramsey Bell will convene for the Pharmacy Well-Being Subcommittee.*
15	*Ms. Carrillo will add uniformed service (coast guard and public health service) regulations to the September 2022 meeting.*
16	*The board will address 12 AAC 52.865(h) at the September 2022 meeting.*
17	*The regulations subcommittee will look at all FY 2023 regulations in advance of the September 2022 meeting.*
18	*Ms. Carrillo sign the adoption order for the large regulations project and send it to Mr. Maiquis.*

State of Alaska 2023 HOLIDAY CALENDAR

State Holidays

Date	Holiday
01/01/2023	New Year's Day (observed 01/02/2023)
01/16/2023	MLK Jr.'s Birthday
02/20/2023	Presidents' Day
03/27/2023	Seward's Day
05/29/2023	Memorial Day
07/04/2023	Independence Day
09/04/2023	Labor Day
10/18/2023	Alaska Day
11/11/2023	Veterans' Day (observed 11/10/2023)
11/23/2023	Thanksgiving Day
12/25/2023	Christmas Day

Please refer to appropriate collective bargaining unit agreement for more information regarding holidays.

Holiday

JANUARY

S	M	T	W	T	F	S
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29	30	31				

FEBRUARY

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MARCH

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APRIL

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MAY

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JUNE

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JULY

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AUGUST

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SEPTEMBER

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OCTOBER

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29	30	31				

NOVEMBER

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DECEMBER

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31						